

**TDMS No.** 99007 - 05  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 08/15/2008  
**Time Report Requested:** 08:34:31  
**First Dose M/F:** 04/21/03 / 04/21/03  
**Lab:** SRI

F1\_R2

**C Number:** C99007B  
**Lock Date:** 08/07/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0



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DAY ON TEST	ANIMAL ID																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	0	
7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	0	
1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0	0	
<hr/>																										
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	0	
<hr/>																										
Necrosis, Focal	3	1	3	1	1	1	1	2	1	2	1	3	2		1	3	2				2	1	2	3	2	
Bile Duct, Hyperplasia																										
Hepatocyte, Hyperplasia, Focal																										
Hepatocyte, Vacuolization Cytoplasmic																										
Kupffer Cell, Pigmentation	3																				3					
<hr/>																										
Mesentery																										
Accessory Spleen																										
Inflammation, Chronic																										
Fat, Necrosis																										
<hr/>																										
Oral Mucosa																										
<hr/>																										
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy		4	2		2				2		1			3	1		1	3	1					1		
Cyst		X	X		X									X												
Acinus, Cytoplasmic Alteration																										
Acinus, Hyperplasia, Focal				2			2							1							3					
<hr/>																										
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy																										
<hr/>																										
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Edema	3		3																							
Ulcer	3		4	4																						
Epithelium, Hyperplasia	2		2	4																						
<hr/>																										
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Erosion	1		2																							

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5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	0	
7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	0	
1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0	0	
.....																										
<b>FISCHER 344 RATS MALE</b> <b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	0	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	0

Epithelium, Hyperplasia ..... 1

Tongue ..... +

Epithelium, Hyperplasia

**CARDIOVASCULAR SYSTEM**

Heart ..... +

Cardiomyopathy ..... 1 1 2 3 2 1 3 1 3 2 1 1 3 1 1 3 1 1 3 1 3 3 3

Thrombosis

**ENDOCRINE SYSTEM**

Adrenal Cortex ..... +

Accessory Adrenal Cortical Nodule ..... 3

Hyperplasia ..... 3 3 2

Hyperplasia, Focal ..... 2

Hypertrophy, Focal ..... 2

Necrosis ..... 1

Vacuolization Cytoplasmic, Focal ..... 1

Adrenal Medulla ..... +

Hyperplasia ..... 2

Islets, Pancreatic ..... +

Hyperplasia

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	7	1	5	0	7	2	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	
	1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males  
(cont...)

Parathyroid Gland	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Angiectasis																							2	
Pars Distalis, Cyst																								
Pars Distalis, Hemorrhage, Chronic																								
Pars Distalis, Hyperplasia, Focal			3												1		1					1		2
Pars Intermedia, Cyst															X							X		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell, Hyperplasia	1			1							2					1						3		
Follicle, Cyst				X																				

**GENERAL BODY SYSTEM**  
 NONE

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Granuloma Sperm																								
Inflammation, Chronic																								3
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																								X
Hyperplasia																								
Hyperplasia, Focal																								
Inflammation, Chronic										2		2		2		2					2		2	2

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7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	0	
1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0	0	

**FISCHER 344 RATS MALE**

**0 PPM**

Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation, Chronic	3												2				3						2		2
Epithelium, Hyperplasia							1								1							1			
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Germinal Epithelium, Atrophy																									4
Interstitial Cell, Hyperplasia	1																					1			

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	
Hemorrhage																									
Hyperplasia										2						4					4				
Myelofibrosis												4													
Lymph Node	+			+			+	+				+											+		
Deep Cervical, Hyperplasia																									
Mediastinal, Ectasia																									
Mediastinal, Hemorrhage																								3	
Mediastinal, Hyperplasia, Lymphoid				2																				3	
Pancreatic, Hemorrhage								1																	
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	M	M	M	+	M	M	M	M	M	M	M	M	M	M	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	
Ectasia																									

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DAY ON TEST	0 0																								
	5 6 6 5 5 7 7 7 7 7 7 7 6 7 7 7 7 4 4 4 7 5 7 7 7																								
FISCHER 344 RATS MALE 0 PPM ANIMAL ID	7 1 5 0 7 2 3 3 3 3 3 3 0 0 3 3 3 0 5 2 2 9 3 3 3																								
	1 1 6 1 5 9 1 1 1 0 0 0 0 6 0 0 0 7 6 2 9 3 0 0 0																								
0 PPM ANIMAL ID	0 0																								
	0 0																								
	0 0																								
	0 0																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

males (cont...)

Hyperplasia, Lymphoid	3		3																						
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+
Fibrosis	3																								
Hematopoietic Cell Proliferation	3												3												
Thymus	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia, Lymphoid																									

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Hyperplasia	3			2												2		2							2		
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Cyst Epithelial Inclusion																									X		
Hyperkeratosis	4								3																		
Inflammation, Chronic																											
Ulcer																			4								
Epidermis, Hyperplasia	3								2																		

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Skeletal Muscle															+											+	+
Atrophy															2												

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	5	6	6	5	5	7	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7
	7	1	5	0	7	2	3	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3
	1	1	6	1	5	9	1	1	1	0	0	0	0	6	0	0	0	7	6	2	9	3	0	0	0
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males  
(cont...)

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Compression														3						3					
Hemorrhage																				3	3				
Necrosis					2																				
Peripheral Nerve														+									+	+	
Spinal Cord														+									+	+	

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																									
Emphysema																									
Hemorrhage																						2			
Infiltration Cellular, Histiocyte				1			1	1	1	1	3	1			1	1	1	3			1	1	1	1	1
Inflammation, Chronic						2			2		3							3					1	2	
Metaplasia, Osseous							1			1		1				2									
Alveolar Epithelium, Hyperplasia							3								2								1	1	
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Foreign Body			X							X			X												X
Inflammation, Chronic			2			1	1			1											1	1			1
Respiratory Epithelium, Hyperplasia			2				1																		

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	5	6	6	5	5	7	7	7	7	7	7	6	7	7	7	7	4	4	4	7	5	7	7	7	
	7	1	5	0	7	2	3	3	3	3	3	0	0	3	3	3	0	5	2	2	9	3	3	3	
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<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>ANIMAL ID</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

**males (cont...)**

Respiratory Epithelium, Metaplasia, Squamous

Trachea +

**SPECIAL SENSES SYSTEM**

Eye +  
 Cataract 3  
 Retina, Degeneration 3

Harderian Gland +  
 Hyperplasia, Focal

**URINARY SYSTEM**

Kidney +  
 Inflammation, Suppurative  
 Nephropathy 2 1 1 2 1 1 1 1 1 2 1 1 3 1 1 1 1 1 1 1 1 1 1 1  
 Renal Tubule, Accumulation, Hyaline Droplet 3  
 Renal Tubule, Necrosis  
 Renal Tubule, Pigmentation 2 2

Urinary Bladder +

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 Lab: SRI

DAY ON TEST	0																								* TOTALS		
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	7			
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1			
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6			
<b>FISCHER 344 RATS MALE</b>																											
<b>0 PPM</b>																											
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	5			
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0		
Necrosis, Focal																									3	1	3.0
Bile Duct, Hyperplasia	2	1	1	2	3	1		2		1	1	2	1	3		3	1	2	2	3	1	1	3	2	3		
Hepatocyte, Hyperplasia, Focal																									2	1	2.0
Hepatocyte, Vacuolization Cytoplasmic																										3	2.5
Kupffer Cell, Pigmentation																										2	3.0
Mesentery																									+		
Accessory Spleen																										+	
Inflammation, Chronic																											9
Fat, Necrosis																											3
																									2		3.0
																										3	2.3
Oral Mucosa																									+		1
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Atrophy	3		2				2	1				1												1	2		
Cyst	X	X												X		X	X	X									
Acinus, Cytoplasmic Alteration																											10
Acinus, Hyperplasia, Focal																									2		3.0
																										2	1.7
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Atrophy																										1	2.0
																										1	
																										3	
																											3
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Edema																											3.0
Ulcer																											3.7
Epithelium, Hyperplasia																										1	2.2
																										2	
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Erosion																										1	1.3

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 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008

Time Report Requested: 08:34:31

First Dose M/F: 04/21/03 / 04/21/03

Lab: SRI

Table with columns for DAY ON TEST, ANIMAL ID, and individual animal data for FISCHER 344 RATS MALE at 0 PPM. Includes a \* TOTALS column.

Summary table for Epithelium, Hyperplasia and Tongue Epithelium, Hyperplasia, showing counts and mean severity grades.

CARDIOVASCULAR SYSTEM

Table for Cardiovascular System showing Heart, Cardiomyopathy, and Thrombosis with counts and mean severity grades.

ENDOCRINE SYSTEM

Table for Endocrine System showing Adrenal Cortex (various lesions), Adrenal Medulla Hyperplasia, and Islets, Pancreatic Hyperplasia with counts and mean severity grades.

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
l .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
Page 12
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

DAY ON TEST	0 0																							* TOTALS	
	7 7 7 7 5 7 7 7 5 5 7 7 7 7 7 7 7 6 7 7 7 7 7																								
																							2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3		
																							6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0		

**FISCHER 344 RATS MALE**

**0 PPM**

ANIMAL ID

Parathyroid Gland	+ +																							49																								
Pituitary Gland	+ +																							50																								
Pars Distalis, Angiectasis																							2	2.0																								
Pars Distalis, Cyst	X		X		X		X		X		X		X		X		X		X		X		X		X		7	1.0																				
Pars Distalis, Hemorrhage, Chronic																							1	1.0																								
Pars Distalis, Hyperplasia, Focal	1						1		2		3		3		1		2		1		3				14		1.8																					
Pars Intermedia, Cyst	X																								3																						3	
Thyroid Gland	+ +																							50																								
C-cell, Hyperplasia																							1	1.4																								
Follicle, Cyst																							1	3																								

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Epididymis	+ +																							50					
Granuloma Sperm																							3	3.0					
Inflammation, Chronic																							1	3.0					
Preputial Gland	+ +																							50					
Cyst																							X	2					
Hyperplasia																							2	1.5					
Hyperplasia, Focal																							1	2.0					
Inflammation, Chronic	2		3		2		2		2		2		2		2		2		2		2		2		2		19		2.1

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 + .. Tissue examined microscopically  
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 1-4 .. Lesion qualified as:  
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 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1		
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6		
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	<b>* TOTALS</b>

Hyperplasia, Lymphoid																										3	3	4	3.0
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+				49
Fibrosis																													1 3.0
Hematopoietic Cell Proliferation																													2 3.0
Thymus	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+				48	
Hyperplasia, Lymphoid																										3			1 3.0

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+				50
Hyperplasia																												2 2	7 2.1
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+				50	
Cyst Epithelial Inclusion																													1
Hyperkeratosis																													4 3.0
Inflammation, Chronic																													2 2.5
Ulcer																													1 4.0
Epidermis, Hyperplasia																													5 2.6

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+				50
Skeletal Muscle																													3
Atrophy																													1 2.0

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 Page 15

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	7	5	7	7	7	5	5	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7
	3	3	3	3	8	3	3	3	6	6	3	1	3	3	3	3	3	3	6	2	2	2	3	1	0
	0	0	0	0	3	0	0	0	1	3	1	1	0	0	0	0	0	0	3	9	9	9	0	6	
<b>FISCHER 344 RATS MALE</b> <b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
	<b>* TOTALS</b>																								

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Compression																										2 3.0
Hemorrhage																										2 3.0
Necrosis																										1 2.0
Peripheral Nerve																					+					4
Spinal Cord																					+					4

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst													X													1
Emphysema																										1 2.0
Hemorrhage																										1 2.0
Infiltration Cellular, Histiocyte																										34 1.2
Inflammation, Chronic																										16 1.7
Metaplasia, Osseous																										5 1.2
Alveolar Epithelium, Hyperplasia																										8 1.8
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Foreign Body																										6
Inflammation, Chronic																										12 1.3
Respiratory Epithelium, Hyperplasia																										5 1.4

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	0 0																								
	5 5 7 6 6 6 7 7 7 5 7 5 6 7 3 7 7 7 7 6 7 6 7 7 6																								
FISCHER 344 RATS MALE 3000 PPM ANIMAL ID	0 0																								
	0 0																								
5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6																									
1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																									

males  
(cont...)

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum Edema	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis																									
Basophilic Focus			X	X			X	X	X		X	X		X	X		X	X	X	X		X	X		
Clear Cell Focus								X	X		X			X	X		X	X				X	X		
Degeneration, Cystic																									
Eosinophilic Focus				X		X																			
Hematopoietic Cell Proliferation																									
Hemorrhage	4																								
Hepatodiaphragmatic Nodule				X		X						X		X									X		
Infiltration Cellular, Mixed Cell										1															

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TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008

Time Report Requested: 08:34:31

First Dose M/F: 04/21/03 / 04/21/03

Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
	5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7	6	7	7	6									
	0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3	8												
	6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1	4												
.....																																					
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
<b>3000 PPM</b>	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6				
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		
																																				<b>males</b>	
																																				<b>(cont...)</b>	
.....																																					
Mixed Cell Focus			X	X			X	X	X	X								X			X																
Necrosis, Focal																																					
Bile Duct, Hyperplasia		2	1	1	1	1		1	1	1		1	1	3	1	2	2		2		2	1	2	3													
Centrilobular, Necrosis	4																																				
Hepatocyte, Degeneration			1	1			1	1	1									1	1		1	1															
Hepatocyte, Hypertrophy									1	1							1	1	2			1															
Hepatocyte, Vacuolization Cytoplasmic															3																			3			
.....																																					
Mesentery	+			+									+					+																+			
Fat, Necrosis	4			3									2					3																			
.....																																					
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy					2							3						2	2	3	2	1									2	4					
Cyst				X						X	X								X	X	X																
Acinus, Cytoplasmic Alteration										3																											
.....																																					
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Atrophy																	2																				
.....																																					
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Edema						2																															
Erosion						1																															
Inflammation, Chronic Active																																					
Ulcer											3	3		3																						3	
Epithelium, Hyperplasia		1									2	3																								3	
.....																																					
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Erosion						1																															
Ulcer											3							3																		3	

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	0 0																								
	5 5 7 6 6 6 7 7 7 5 7 5 6 7 3 7 7 7 7 6 7 6 7 7 6																								
FISCHER 344 RATS MALE 3000 PPM ANIMAL ID	0 0																								
	0 0																								
3000 PPM	5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

males  
(cont...)

Tongue

+

**CARDIOVASCULAR SYSTEM**

Blood Vessel

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy	3	1	2	1	2		3	3	1	1		1		1	1		2	3	3	1	3		3	3	2

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule							3									3		3							
Degeneration, Fatty																									
Hyperplasia																								2	
Hyperplasia, Focal											1														
Hypertrophy, Focal																									
Vacuolization Cytoplasmic, Focal										2		1													
Vacuolization Cytoplasmic, Diffuse															3										

Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia							2											1							1

Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																									

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	ANIMAL ID																									males (cont...)		
	0 5 0 6	0 5 6 5	0 7 3 0	0 6 9 6	0 6 4 5	0 6 5 6	0 7 2 9	0 7 2 9	0 7 2 9	0 5 3 0	0 7 3 1	0 5 6 6	0 7 3 2	0 3 5 9	0 7 3 5	0 7 3 0	0 7 3 0	0 6 3 8	0 7 3 0	0 6 4 0	0 7 3 2	0 6 4 1	0 7 3 1	0 6 3 4				
<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>3000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Parathyroid Gland	+	M	+	+	+	+	+	+	+	+	+	+	+	M	+	M	+	+	+	+	+	+	+	+	+	+	+
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Angiectasis										1				4													
Pars Distalis, Hyperplasia, Focal					2					2									3			2					
Pars Intermedia, Cyst																										X	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell, Hyperplasia		1								2																	
Follicle, Cyst																											

**GENERAL BODY SYSTEM**

Tissue NOS																											
Hemorrhage																											

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Inflammation, Acute																												
Inflammation, Chronic																											2	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Cyst																												
Hyperplasia, Focal																												
Inflammation, Chronic					2					2	3															2	3	2

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	7	6	6	6	7	7	7	5	7	5	6	7	3	7	7	7	7	6	7	6	7	7
	0	6	3	9	4	5	2	2	2	3	3	7	3	2	5	3	3	3	3	7	3	4	3	3
	6	5	0	6	5	6	9	9	9	0	1	6	2	9	5	0	0	0	0	8	0	2	1	1

  

FISCHER 344 RATS MALE 3000 PPM ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	

males  
(cont...)

Hyperplasia, Lymphoid  
Infiltration Cellular, Mixed Cell

2 2 2

Spleen  
Accessory Spleen  
Fibrosis  
Hematopoietic Cell Proliferation  
Infiltration Cellular, Mixed Cell  
Metaplasia, Lipocyte

+  
 X  
 2 2 1 2 1 2  
 2

Thymus  
Cyst  
Fibrosis  
Epithelial Cell, Hyperplasia

+ + + + + + + + + + + + + + + M + + + + + + +  
 X

INTEGUMENTARY SYSTEM

Mammary Gland  
Hyperplasia

+  
 3 2 3

Skin  
Cyst Epithelial Inclusion  
Edema  
Hyperkeratosis

+  
 X  
 2 3  
 4

MUSCULOSKELETAL SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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 I .. Insufficient tissue  
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 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 23  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                    | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | 5 5 7 6 6 6 7 7 7 5 7 5 6 7 3 7 7 7 7 6 7 6 7 7 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>3000 PPM<br>ANIMAL ID | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

males  
(cont...)

|                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Skeletal Muscle | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**NERVOUS SYSTEM**

|                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Brain            | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Compression      | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage       | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis         | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Peripheral Nerve | + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Spinal Cord      | + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**RESPIRATORY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Lung                              | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Foreign Body                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                        | 2 2 3 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Histiocyte | 3 1 1 3 1 1 3 1 1 1 1                             |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Suppurative         | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Chronic             | 1 1 1 1 1 1 1 1 1                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Metaplasia, Osseous               | 1 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Alveolar Epithelium, Hyperplasia  | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 5 | 5 | 7 | 6 | 6 | 6 | 7 | 7 | 7 | 5 | 7 | 5 | 6 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |
|                              | 0 | 6 | 3 | 9 | 4 | 5 | 2 | 2 | 2 | 3 | 3 | 7 | 3 | 2 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 4 | 3 | 3 | 8 |
|                              | 6 | 5 | 0 | 6 | 5 | 6 | 9 | 9 | 9 | 0 | 1 | 6 | 2 | 9 | 5 | 0 | 0 | 0 | 0 | 8 | 0 | 2 | 1 | 1 | 4 |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0                            | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>3000 PPM</b>              | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body                        |   |   |   |   | X |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Inflammation, Chronic               | 1 |   |   |   | 1 |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |
| Retina, Degeneration  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**URINARY SYSTEM**

|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                 |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nephropathy                          | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |   |
| Renal Tubule, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation           |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |
| Transitional Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| Urethra                              |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Angiectasis                          |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

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 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                     | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5   | 5         | 7 | 6 | 6 | 6 | 7 | 7 | 7 | 5 | 7 | 5 | 6 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |   |
| 0   | 6         | 3 | 9 | 4 | 5 | 2 | 2 | 2 | 3 | 3 | 7 | 3 | 2 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 4 | 3 | 3 | 8 |   |
| 6   | 5         | 0 | 6 | 5 | 6 | 9 | 9 | 9 | 0 | 1 | 6 | 2 | 9 | 5 | 0 | 0 | 0 | 0 | 8 | 0 | 2 | 1 | 1 | 4 |   |
| <b>FISCHER 344 RATS MALE</b><br><b>3000 PPM</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|   | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |
|   | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Urinary Bladder Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

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 2) Mild 4) Marked

Page 26

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7               | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |
|                              | 3               | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |
|                              | 1               | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |
| <b>FISCHER 344 RATS MALE</b> | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>3000 PPM</b>              | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                    | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                              | 7               | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
|                              | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
|                              | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

ALIMENTARY SYSTEM

|                                   |              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
|-----------------------------------|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus                         | +            | I | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Large, Cecum<br>Edema   | +            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
|                                   | <b>1 2.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |
| Intestine Large, Colon            | +            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48    |
| Intestine Large, Rectum           | +            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Intestine Small, Duodenum         | +            | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Small, Ileum            | +            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49    |
| Intestine Small, Jejunum          | +            | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48    |
| Liver                             | +            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |
| Angiectasis                       |              |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Basophilic Focus                  | X            |   |   | X | X | X | X | X | X | X | X | X | X | X | X | X | X |   |   |   |   | X | X |   | 33    |
| Clear Cell Focus                  | X            |   |   |   |   |   | X | X | X |   |   |   | X | X |   |   |   |   |   |   |   |   | X | X | 17    |
| Degeneration, Cystic              |              | 1 |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 1.5 |
| Eosinophilic Focus                |              |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5     |
| Hematopoietic Cell Proliferation  |              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 1.0 |
| Hemorrhage                        |              |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 2 |   |   |   |   |   | 2 | 2 |   |   | 6 2.2 |
| Hepatodiaphragmatic Nodule        | X            |   |   |   |   |   | X |   |   |   |   | X | X |   | X |   |   |   |   |   | X |   | X |   | 13    |
| Infiltration Cellular, Mixed Cell |              |   |   |   |   |   | 1 |   |   |   |   |   | 3 |   |   |   | 3 |   |   |   |   |   |   |   | 6 1.7 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                    | 0  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |        |
|--|--|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|---|---|---|----------|--------|
|  | 7 7 7 5 7 5 7 7 7 7 7 7 7 7 7 6 7 4 6 7 7 5 6<br>3 3 1 1 2 6 2 2 2 2 2 3 2 3 3 3 3 6 3 3 6 3 3 0 4<br>1 1 1 7 9 3 9 9 9 9 9 1 3 1 1 1 1 3 0 7 6 1 1 9 9  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |        |
| FISCHER 344 RATS MALE<br>3000 PPM<br>ANIMAL ID | 0  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |        |
|  | 0<br>0 0<br>7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9<br>6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          |        |
| Mixed Cell Focus                               | X  |   |   |   | X |   | X | X |   | X | X | X |  | X | X | X |   | X |   | X | X |   |   |   | 21       |        |
| Necrosis, Focal                                |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 1        | 2 2.0  |
| Bile Duct, Hyperplasia                         | 1  | 3 | 3 | 1 | 1 |   | 1 | 2 | 1 | 2 | 1 | 1 |  | 1 | 2 | 1 |   | 1 | 2 |   | 3 | 1 |   | 1 | 38 1.5   |        |
| Centrilobular, Necrosis                        |  |   |   | 2 |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 2 3.0  |
| Hepatocyte, Degeneration                       | 1  |   |   |   | 1 |   |   | 1 | 1 | 1 | 1 | 1 |  | 1 |   | 1 | 1 |   | 1 |   |   | 2 | 2 |   | 22 1.1   |        |
| Hepatocyte, Hypertrophy                        | 2  |   |   |   | 2 |   | 1 | 2 | 1 | 1 | 2 | 1 |  | 1 | 2 | 1 |   |   |   |   |   | 1 | 2 |   | 19 1.4   |        |
| Hepatocyte, Vacuolization Cytoplasmic          |  |   |   |   |   | 4 |   |   |   |   |   |   |  |   |   |   |   |   | 3 |   |   |   |   |   | 4 3.3    |        |
| Mesentery                                      |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 9        | 5 2.8  |
| Fat, Necrosis                                  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 2        |        |
| Pancreas                                       |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 50     |
| Atrophy  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 19 2.2 |
| Cyst   | X  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 12       |        |
| Acinus, Cytoplasmic Alteration                 |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   | 3        | 3 3.0  |
| Salivary Glands                                |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 49     |
| Atrophy  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 2 1.5  |
| Stomach, Forestomach                           |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 50     |
| Edema  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 5 3.0  |
| Erosion  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 1 1.0  |
| Inflammation, Chronic Active                   |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 1 3.0  |
| Ulcer  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 8 3.5  |
| Epithelium, Hyperplasia                        |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 7 2.4  |
| Stomach, Glandular                             |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 50     |
| Erosion  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 2 2.0  |
| Ulcer  |  |   |   |   |   |   |   |   |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |          | 3 2.7  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 28



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |
|             | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |   |
|             | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |   |

**FISCHER 344 RATS MALE**  
 3000 PPM

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1               |
| 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0               |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |              |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--------------|
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | M | + | + | +         | <b>45</b>    |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +         | <b>50</b>    |
| Pars Distalis, Angiectasis        |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |           | <b>4 2.0</b> |
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |           | <b>6 2.0</b> |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |           | <b>2</b>     |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |              |
| C-cell, Hyperplasia               |   | 1 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>4 1.3</b> |
| Follicle, Cyst                    |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>     |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |              |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Tissue NOS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1</b>     |
| Hemorrhage |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 3.0</b> |

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +         | <b>50</b>     |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |           | <b>1 3.0</b>  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |           | <b>2 2.0</b>  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |           | <b>1</b>      |
| Hyperplasia, Focal    |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 1.0</b>  |
| Inflammation, Chronic |   |   |   |   |   |   | 3 |   |   |   |   | 2 |   |   |   | 3 |   |   |   |   |   |   |   |           | <b>10 2.4</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |
|------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
|                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0 |
|                              | 7         | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |          |   |
|                              | 3         | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4        |   |
|                              | 1         | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9        |   |
| <b>FISCHER 344 RATS MALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
| <b>3000 PPM</b>              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|                              | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0        |   |
|                              | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |   |

|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Prostate                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Inflammation, Chronic          |   | 2 | 2 |   | 1 |   |   |   |   |   |   | 2 | 1 | 3 |   |   |   | 2 | 3 |   |   | 2 |   |   |   | 15 2.3 |
| Epithelium, Hyperplasia        |   |   |   |   | 1 |   |   |   |   | 1 |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 1.0  |
| Seminal Vesicle                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Testes                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |
| Germinal Epithelium, Atrophy   |   |   |   | 4 |   | 3 |   |   |   |   |   |   |   |   | 3 |   |   | 2 | 3 |   |   |   |   |   |   | 8 3.0  |
| Interstitial Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   | 2 |   |   |   | 2 |   | 6 1.7  |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50    |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   | 3 |   |   |   |   |   |    | 4 2.8 |
| Myelofibrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |    | 2 2.0 |
| Lymph Node                         |   | + |   |   |   |   | + |   |   |   | + |   | + |   |   |   |   | + |   |   | + |   |   | + | 11 |       |
| Mediastinal, Hemorrhage            |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 3 |   |   |   |   |   |    | 2 2.5 |
| Mediastinal, Hyperplasia, Lymphoid |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |    | 1 3.0 |
| Mediastinal, Pigmentation          |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 3.0 |
| Pancreatic, Ectasia                |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 3.0 |
| Pancreatic, Hyperplasia, Lymphoid  |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |
| Lymph Node, Mandibular             | M | M | M | M | M | M | M | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 1  |       |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 49    |
| Ectasia                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2 1.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 31

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |   |
| <b>FISCHER 344 RATS MALE</b> | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |                 |   |
| <b>3000 PPM</b>              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0               | 4 |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9               |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1               |   |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |   |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0               |   |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Hyperplasia, Lymphoid Infiltration Cellular, Mixed Cell |   |   |   |   | 3 |   |   |   |   |   | 2 |   |   | 2 |   |   |   |   | 2 | 2 | 2 |   | 2 | 2 | 11 | 2.1 |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   | 1  | 4.0 |
| Spleen  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Accessory Spleen  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |     |
| Fibrosis  |   |   |   | 2 |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 1.5 |
| Hematopoietic Cell Proliferation                        |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   | 8  | 1.8 |
| Infiltration Cellular, Mixed Cell                       |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 4 |   |   |   |   |   |   |   |   | 3  | 3.0 |
| Metaplasia, Lipocyte                                    |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Thymus  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |     |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |     |
| Fibrosis  |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Epithelial Cell, Hyperplasia                            |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |

INTEGUMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |    |     |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|----|-----|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |    |     |
| Hyperplasia               |   |   | 1 |   |   |   |   |   | 3 | 4 |   |   |   | 2 |   |   | 2 | 4 |   |   | 1 | 4 |   | 3 |    | 1   | 13 | 2.5 |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |    |     |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3  |     |    |     |
| Edema                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 2.5 |    |     |
| Hyperkeratosis            |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 3.5 |    |     |

MUSCULOSKELETAL SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                              | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |          |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4        |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9        |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>3000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0        |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |    |

**NERVOUS SYSTEM**

|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |    |     |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|----|-----|
| Brain            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |    |     |
| Angiectasis      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 2.0 |    |     |
| Compression      | 2 | 2 | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 4 | 4 | 4 | 2 |   |   |   |     | 10 | 3.0 |
| Hemorrhage       |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 1 |   |   |   |   |   | 4 | 2.5 |    |     |
| Necrosis         |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 2 |   | 3 |   |   |   | 4 | 2.5 |    |     |
| Peripheral Nerve |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |     |    |     |
| Spinal Cord      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |     |    |     |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |     |     |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|-----|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50  |     |     |
| Foreign Body                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | 1 |    |     |     |     |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4  | 2.3 |     |     |
| Infiltration Cellular, Histiocyte | 2 | 1 | 1 | 1 |   |   | 1 |   |   | 1 | 1 | 1 |   |   | 1 | 1 | 1 |   |   | 1 | 1 |   |   | 24 | 1.3 |     |     |
| Inflammation, Suppurative         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 2.0 |     |     |
| Inflammation, Chronic             |   |   |   |   |   |   |   |   |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   | 1  | 3   | 10  | 1.2 |
| Metaplasia, Osseous               |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   | 3  |     | 1.0 |     |
| Alveolar Epithelium, Hyperplasia  | 1 |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   | 3 |    | 1.3 |     |     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 33

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
|                              | 7 | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |   |   |                 |  |
|                              | 3 | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4 |   |                 |  |
|                              | 1 | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9 |   |                 |  |
| .....                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |  |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
| <b>3000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |                 |  |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |                 |  |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |                 |  |
| .....                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |  |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |  |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|--|
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |  |
| Foreign Body                        |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 5   |  |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4   |  |
| Respiratory Epithelium, Hyperplasia | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1.0 |  |
| .....                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |  |

**SPECIAL SENSES SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|--|
| Eye                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   |  |
| Retina, Degeneration  |   | 2 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4.0 |  |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3   |  |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3   |  |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2.3 |  |
| .....                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
| Harderian Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   |  |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2.0 |  |

**URINARY SYSTEM**

|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|--|
| Kidney                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50  |  |
| Cyst                                 |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2   |  |
| Nephropathy                          | 2 | 3 | 1 | 1 | 1 | 4 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 2 | 1 | 1 | 1 | 2 | 1 | 1 |   |   |     |  |
| Renal Tubule, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 49  |  |
| Renal Tubule, Pigmentation           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1.4 |  |
| Transitional Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   |  |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3.0 |  |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3.0 |  |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2   |  |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2.0 |  |
| .....                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |  |
| Urethra                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   |  |
| Angiectasis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   |  |
|                                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3.0 |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 34

**TDMS No.** 99007 - 05  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 08/15/2008  
**Time Report Requested:** 08:34:31  
**First Dose M/F:** 04/21/03 / 04/21/03  
**Lab:** SRI

|  |                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| DAY ON TEST  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |    |
|  | 7               | 7 | 7 | 5 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 6 | 7 | 7 | 5 | 6 |    |
|  | 3               | 3 | 1 | 1 | 2 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 6 | 3 | 3 | 0 | 4  |
|  | 1               | 1 | 1 | 7 | 9 | 3 | 9 | 9 | 9 | 9 | 9 | 1 | 3 | 1 | 1 | 1 | 1 | 3 | 0 | 7 | 6 | 1 | 1 | 9 | 9  |
| <b>FISCHER 344 RATS MALE</b><br>ANIMAL ID<br><b>3000 PPM</b> | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |    |
|  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0  |
|  | 0               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1  |
|  | 7               | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0  |
|  | 6               | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0  |
|  | <b>* TOTALS</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
| Urinary Bladder Hemorrhage                                   | +               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|  | <b>1 1.0</b>    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 35

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS MALE | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 |
| 9000 PPM              | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 |
| ANIMAL ID             | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 |
|                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                       | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                       | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

males (cont...)

ALIMENTARY SYSTEM

|                                   |   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
|-----------------------------------|---|---|---|--|--|---|---|---|---|--|--|---|---|---|--|--|--|---|---|---|---|---|---|---|--|
| Esophagus                         | + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Large, Cecum<br>Edema   | + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Large, Colon            | + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Large, Rectum           | + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Small, Duodenum         | + + + + + + + + + + A + + + + + + + + + + + + + + + + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Small, Ileum            | + + + A + + + + + A + + + + + + + + + + + + + + + + + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Intestine Small, Jejunum          | + + + A + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Liver                             | + |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Angiectasis                       |   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Basophilic Focus                  |   | X |   |  |  | X | X | X |   |  |  | X |   |   |  |  |  | X | X | X |   |   |   | X |  |
| Clear Cell Focus                  |   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Degeneration, Cystic              |   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Eosinophilic Focus                | X   |   | X |  |  | X | X | X | X |  |  | X | X | X |  |  |  |   | X | X | X | X | X | X |  |
| Hepatodiaphragmatic Nodule        |   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |
| Infiltration Cellular, Mixed Cell |   | X |   |  |  |   |   |   |   |  |  | X |   |   |  |  |  |   |   |   |   |   | X | X |  |
| Mixed Cell Focus                  | X   |   | X |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   | 1 |  |
| Necrosis, Focal                   | 3   |   |   |  |  |   |   |   |   |  |  |   |   |   |  |  |  |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                              | FISCHER 344 RATS MALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |
|--|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|  | ANIMAL ID             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| 9000 PPM                                 | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |
|  | 7                     | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7                  |
|  | 3                     | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 | 3                  |
|  | 0                     | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 | 1                  |
| Bile Duct, Hyperplasia                   | 1                     | 1 | 1 |   | 1 | 1 | 1 | 1 | 3 |   | 1 | 3 | 2 | 4 | 3 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 |                    |
| Hepatocyte, Degeneration                 |                       |   |   | 2 |   | 1 | 1 | 1 |   |   | 1 |   |   |   |   | 1 | 2 |   | 1 | 2 | 2 |   | 3 | 2 | 3 |                    |
| Hepatocyte, Hypertrophy                  | 2                     |   | 3 |   |   | 2 | 1 | 1 |   |   | 2 |   |   |   |   | 2 | 2 |   | 3 | 2 | 1 |   | 4 | 2 | 3 |                    |
| Hepatocyte, Vacuolization Cytoplasmic    |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Kupffer Cell, Pigmentation               |                       |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Mesentery                                |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Accessory Spleen                         |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Angiectasis                              |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Hemorrhage                               |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Fat, Necrosis                            |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Pancreas                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Atrophy                                  |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Cyst                                     |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Necrosis                                 |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Acinus, Hyperplasia, Focal               |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Salivary Glands                          |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Atrophy                                  |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Infiltration Cellular, Polymorphonuclear |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Stomach, Forestomach                     |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Edema                                    |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Hyperplasia, Squamous                    |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Inflammation, Chronic Active             |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Perforation                              |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Ulcer                                    |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Epithelium, Hyperplasia                  |                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 37

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 |   |
|                              | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 3 |   |
|                              | 0 | 0 | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 1 |   |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                              | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

males  
(cont...)

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stomach, Glandular Erosion | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ulcer                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Epithelium, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 2 |   |   |   | 2 | 1 | 3 |   |   |   |   |   |   |   |   |   |   |
| Thrombosis     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**ENDOCRINE SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hypertrophy, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vacuolization Cytoplasmic, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vacuolization Cytoplasmic, Diffuse |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Adrenal Medulla                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Islets, Pancreatic                 | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 38  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                    | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |  |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|--|
|  | 7 7 7 3 7 7 7 7 6 5 5 4 6 7 6 7 7 7 7 7 7 5 7 7 7 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
| FISCHER 344 RATS MALE<br>9000 PPM<br>ANIMAL ID | 3 3 3 1 2 3 3 3 9 9 5 3 4 3 9 3 3 0 2 2 2 3 2 2 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
|  | 0 0 0 6 4 0 0 0 6 4 6 1 4 0 6 0 0 9 9 9 9 4 9 9 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |  |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |  |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |  |
|  | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  |  |
|  | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |  |
|  | 1   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                    |  |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Pars Distalis, Angiectasis        |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Pars Distalis, Cyst               |   |   |   |   |   |   | X |   | X |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | X |  |
| Pars Distalis, Hyperplasia, Focal |   |   | 1 |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 2 |   | X |  |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |  |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |  |
| C-cell, Hyperplasia               |   |   |   |   |   | 1 |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |  |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |  |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Tissue NOS |  |  |  |  |  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Chronic |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |  |
| Hyperplasia           |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Inflammation, Chronic |   |   | 2 | 2 |   |   |   |   | 3 |   |   |   | 2 |   | 3 | 2 | 2 | 2 |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                    | 7 7 7 3 7 7 7 7 6 5 5 4 6 7 6 7 7 7 7 7 5 7 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>ANIMAL ID | 3 3 3 1 2 3 3 3 9 9 5 3 4 3 9 3 3 0 2 2 2 3 2 2 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0 0 0 6 4 0 0 0 6 4 6 1 4 0 6 0 0 9 9 9 4 9 9 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 9000 PPM                           | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

males  
(cont...)

|                                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Prostate                       | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Chronic          | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Epithelium, Hyperplasia        | 1 2 1 2 2 1 2                                     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Seminal Vesicle                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Testes                         | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Germinal Epithelium, Atrophy   | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interstitial Cell, Hyperplasia | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**HEMATOPOIETIC SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow                        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                        | 3 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Histiocyte  | 3 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node                         | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Ectasia               | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hemorrhage            | 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hyperplasia, Lymphoid | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pancreatic, Ectasia                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pancreatic, Hemorrhage             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mandibular             | M M + M |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mesenteric             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Ectasia                            | 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
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 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        | 0   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                            |   |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------------|---|
|                                    | 7 7 7 3 7 7 7 7 6 5 5 4 6 7 6 7 7 7 7 7 7 5 7 7 7 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                            |   |
| FISCHER 344 RATS MALE<br>ANIMAL ID | 3 3 3 1 2 3 3 3 9 9 5 3 4 3 9 3 3 0 2 2 2 3 2 2 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                            |   |
|                                    | 0 0 0 6 4 0 0 0 6 4 6 1 4 0 6 0 0 9 9 9 9 4 9 9 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                            |   |
| <b>9000 PPM</b>                    | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | <b>males<br/>(cont...)</b> |   |
|                                    | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                            |   |
|                                    | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                            | 1 |
|                                    | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                            | 0 |
|                                    | 1   | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |                            | 5 |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|--|--|--|--|--|
| Hemorrhage                        | 2 |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Hyperplasia, Lymphoid             |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 2 |   |   |   | 2 |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Spleen                            | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |  |  |  |  |  |  |  |
| Fibrosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | 1 |  |  |  |  |  |  |  |  |
| Hemorrhage                        |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Hyperplasia, Lymphoid             | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Mixed Cell | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Necrosis                          |   |   |   |   | 4 |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |  |  |  |  |  |  |  |
| Thymus                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |  |  |  |  |  |  |  |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia               |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperkeratosis            |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |
| Epidermis, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |

**MUSCULOSKELETAL SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              | 7                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                              | 3                      |   |   |   |   | 1 |   |   |   |   | 2 |   |   |   |   | 3 |   |   |   |   | 9 |   |   |   |   |   |
|                              | 0                      |   |   |   |   | 6 |   |   |   |   | 4 |   |   |   |   | 0 |   |   |   |   | 9 |   |   |   |   |   |
| <b>FISCHER 344 RATS MALE</b> | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>9000 PPM</b>              | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>ANIMAL ID</b>             | 1                      | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
|                              | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                              | 1                      | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
|                              | <b>males (cont...)</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Bone +

Skeletal Muscle +

**NERVOUS SYSTEM**

Brain +  
 Compression  
 Hemorrhage 4 1  
 Hydrocephalus  
 Necrosis 3

Peripheral Nerve + + +

Spinal Cord + + +

**RESPIRATORY SYSTEM**

Lung +  
 Edema  
 Foreign Body X  
 Hemorrhage 3  
 Infiltration Cellular, Histiocyte 1 1 1 1 1 3 3 1  
 Inflammation, Chronic 1 1 1 2 3 1 1 1 1  
 Alveolar Epithelium, Hyperplasia 1

Nose +

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 42

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |   |  |
|------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|--|
|                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    | 0 |  |
| 7                            | 7         | 7 | 3 | 7 | 7 | 7 | 7 | 6 | 5 | 5 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 0 | 0 |                    |   |  |
| 3                            | 3         | 3 | 1 | 2 | 3 | 3 | 3 | 9 | 9 | 5 | 3 | 4 | 3 | 9 | 3 | 3 | 0 | 2 | 2 | 2 | 3 | 2 | 2 | 3 | 0 | 0                  |   |  |
| 0                            | 0         | 0 | 6 | 4 | 0 | 0 | 0 | 6 | 4 | 6 | 1 | 4 | 0 | 6 | 0 | 0 | 9 | 9 | 9 | 9 | 4 | 9 | 9 | 1 | 0 | 0                  |   |  |
| .....                        |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |   |  |
| <b>FISCHER 344 RATS MALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |  |
| <b>9000 PPM</b>              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |  |
|                              | 1         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  | 1 |  |
|                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  | 0 |  |
|                              | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 0                  |   |  |

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Foreign Body                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | X |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Eye                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Retina, Degeneration | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| .....                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Harderian Gland      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hyperplasia, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |  |

**URINARY SYSTEM**

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Kidney                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Infarct                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |  |
| Nephropathy                | 1 | 1 | 1 |   | 1 | 2 | 1 | 1 | 1 |   | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 |   |   |   |  |
| Renal Tubule, Necrosis     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |  |
| Renal Tubule, Pigmentation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |  |
| .....                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Urinary Bladder            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008

Time Report Requested: 08:34:31

First Dose M/F: 04/21/03 / 04/21/03

Lab: SRI

| DAY ON TEST                              |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0             |  |
|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|--|
| ANIMAL ID                                |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0             |  |
| 9000 PPM                                 |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |               |  |
| Bile Duct, Hyperplasia                   |  | 1 | 2 | 3 |   | 3 | 2 | 2 | 2 | 2 | 4 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 |   | 1 | 2 | 1 | 1 | <b>45 1.6</b> |  |
| Hepatocyte, Degeneration                 |  |   | 2 |   |   | 1 | 2 |   |   |   |   | 2 | 2 | 2 | 2 | 2 | 3 | 1 | 2 | 2 |   | 1 | 2 | 2 | 2 | <b>30 1.8</b> |  |
| Hepatocyte, Hypertrophy                  |  | 1 | 2 |   | 2 |   |   |   |   |   |   | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | 3 |   | 2 | 2 | 2 | 3 | <b>31 1.9</b> |  |
| Hepatocyte, Vacuolization Cytoplasmic    |  |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   | <b>2 3.0</b>  |  |
| Kupffer Cell, Pigmentation               |  |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.0</b>  |  |
| Mesentery                                |  |   | + |   | + |   | + |   |   | + |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   | <b>11</b>     |  |
| Accessory Spleen                         |  |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>      |  |
| Angiectasis                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b>  |  |
| Hemorrhage                               |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 2.5</b>  |  |
| Fat, Necrosis                            |  |   | 3 |   | 4 |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>7 2.7</b>  |  |
| Pancreas                                 |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>     |  |
| Atrophy                                  |  |   | 2 | 2 | 1 |   | 1 | 1 |   |   |   | 2 | 3 | 2 | 1 | 2 |   | 1 | 1 | 3 | 2 |   | 2 | 1 | 2 | <b>25 1.9</b> |  |
| Cyst                                     |  |   |   |   |   | X | X |   |   |   | X |   |   | X |   |   |   |   | X |   |   |   |   |   |   | <b>15</b>     |  |
| Necrosis                                 |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b>  |  |
| Acinus, Hyperplasia, Focal               |  | 3 |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 |   | <b>5 2.2</b>  |  |
| Salivary Glands                          |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |  |
| Atrophy                                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | <b>4 1.8</b>  |  |
| Infiltration Cellular, Polymorphonuclear |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | <b>1 2.0</b>  |  |
| Stomach, Forestomach                     |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |  |
| Edema                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 3.0</b>  |  |
| Hyperplasia, Squamous                    |  |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 2.0</b>  |  |
| Inflammation, Chronic Active             |  |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 4.0</b>  |  |
| Perforation                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>      |  |
| Ulcer                                    |  |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2 3.5</b>  |  |
| Epithelium, Hyperplasia                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3 2.7</b>  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically M .. Missing tissue 1-4 .. Lesion qualified as:  
x .. Lesion present A .. Autolysis precludes evaluation 1) Minimal 3) Moderate  
I .. Insufficient tissue BLANK .. Not examined microscopically 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                    | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|  | 7 7 7 5 7 7 6 7 6 6 7 7 7 7 7 7 6 7 7 6 7 6 7 7 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| FISCHER 344 RATS MALE<br>9000 PPM<br>ANIMAL ID | 3 3 0 6 0 3 3 3 4 6 2 2 2 2 3 3 9 2 2 1 2 8 2 3 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 1 1 3 3 1 0 5 0 9 3 9 9 9 9 0 0 0 9 9 8 9 8 9 1 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

|                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |     |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Stomach, Glandular      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3 | 1.7 |
| Erosion                 |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2 | 2.0 |
| Ulcer                   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 | 2.0 |
| Epithelium, Hyperplasia | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |     |

**CARDIOVASCULAR SYSTEM**

|                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Heart          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 39 | 2.1 |
| Cardiomyopathy | 3 | 3 | 2 |   | 3 |   |   | 3 | 3 | 1 | 2 | 3 | 3 | 2 | 3 | 1 | 3 | 3 |   | 3 | 2 | 2 | 2 | 3 | 1 |    | 1  | 4.0 |
| Thrombosis     |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |

**ENDOCRINE SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Adrenal Cortex                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 14 | 3.0 |
| Accessory Adrenal Cortical Nodule  | 3 |   | 3 |   |   |   |   |   | 3 |   |   |   |   |   | 3 |   | 3 |   | 3 | 3 |   |   |   |   |   |    | 5  | 1.6 |
| Hyperplasia                        |   | 1 |   |   |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 |   |    | 4  | 1.0 |
| Hyperplasia, Focal                 | 1 |   |   |   |   |   |   | 1 |   | 1 |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  | 1.0 |
| Hypertrophy, Focal                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  | 3.0 |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3  | 1.3 |
| Vacuolization Cytoplasmic, Focal   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |    | 1  | 2.0 |
| Vacuolization Cytoplasmic, Diffuse | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |     |
| Adrenal Medulla                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 14 | 1.3 |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   | 3 |   | 1 |   |   |   |   | 1 |   |   | 1 |    |    |     |
| Islets, Pancreatic                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1  | 2.0 |
| Hyperplasia                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |    |    |     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
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TDMS No. 99007 - 05  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
|                              | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |                 |  |
|                              | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5               |  |
|                              | 1 | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9 |                 |  |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
| <b>ANIMAL ID</b>             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |  |
| <b>9000 PPM</b>              | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                 |  |
|                              | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |                 |  |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | <b>* TOTALS</b> |  |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Parathyroid Gland                 | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | M | + | + | + | + | + | + | <b>48</b>    |
| Pituitary Gland                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>    |
| Pars Distalis, Angiectasis        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
| Pars Distalis, Cyst               |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | <b>2 2.5</b> |
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 1 |   | 1 |   |   |   |   | <b>6 1.6</b> |
| Pars Intermedia, Cyst             |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | <b>8 2</b>   |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>    |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>     |
| C-cell, Hyperplasia               |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   | <b>4 1.5</b> |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>     |

| <b>GENERAL BODY SYSTEM</b> |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|----------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| Tissue NOS                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1</b> |

| <b>GENITAL SYSTEM</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   | <b>1 3.0</b>  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3 2.0</b>  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   | X |   |   |   |   | <b>3</b>      |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | <b>2 1.5</b>  |
| Inflammation, Chronic |   |   | 2 |   |   | 2 | 2 |   |   |   |   |   | 2 | 3 |   |   |   |   |   | 2 |   |   |   |   | <b>14 2.2</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                    | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|  | 7 7 7 5 7 7 6 7 6 6 7 7 7 7 7 6 7 7 6 7 6 7 7 6   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| FISCHER 344 RATS MALE<br>9000 PPM<br>ANIMAL ID | 3 3 0 6 0 3 3 3 4 6 2 2 2 2 3 3 9 2 2 1 2 8 2 3 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 1 1 3 3 1 0 5 0 9 3 9 9 9 9 0 0 0 9 9 8 9 8 9 1 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|  | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

|                                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |     |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Prostate                       | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |     |
| Inflammation, Chronic          | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 14 | 2.0 |
| Epithelium, Hyperplasia        | 3 2 1 3 2 1                                     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 5  | 1.4 |
| Seminal Vesicle                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |     |
| Testes                         | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |     |
| Germinal Epithelium, Atrophy   | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3  | 2.0 |
| Interstitial Cell, Hyperplasia | 2 1 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4  | 1.0 |

**HEMATOPOIETIC SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |     |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Bone Marrow                        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |     |
| Hyperplasia                        | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4  | 3.0 |
| Infiltration Cellular, Histiocyte  | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2  | 2.5 |
| Lymph Node                         | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 14 |     |
| Mediastinal, Ectasia               | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2  | 3.0 |
| Mediastinal, Hemorrhage            | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  | 2.0 |
| Mediastinal, Hyperplasia, Lymphoid | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2  | 3.5 |
| Pancreatic, Ectasia                | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  | 3.0 |
| Pancreatic, Hemorrhage             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  | 1.0 |
| Lymph Node, Mandibular             | M |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  |     |
| Lymph Node, Mesenteric             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |     |
| Ectasia                            | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4  | 1.8 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                              | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 |          |
|                              | 3 | 3 | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5        |
|                              | 1 | 1 | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9        |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| ANIMAL ID                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>9000 PPM</b>              | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1        |
|                              | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |     |     |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|-----|
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 1.5 |     |
| Hyperplasia, Lymphoid             | 2 |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   | 2 | 2 | 2 | 2 |   |   |   |   |   |   |   | 9   | 2.0 |
| Spleen                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49  |     |
| Fibrosis                          |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   | 1   | 3.0 |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   | 3 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4   | 2.3 |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   | 3.0 |
| Hyperplasia, Lymphoid             | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2   | 2.5 |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1   | 4.0 |
| Necrosis                          |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3   | 4.0 |
| Thymus                            | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49  |     |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Hyperplasia               | 1 |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   | 1 | 6  | 2.2 |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | 2  |     |
| Hyperkeratosis            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   | 3 | 4 |   |   | 4  | 3.5 |
| Inflammation, Chronic     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 2  | 2.0 |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 4.0 |
| Epidermis, Hyperplasia    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 2 | 3 |   | 4  | 2.8 |

**MUSCULOSKELETAL SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 49

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | FISCHER 344 RATS MALE |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |  |
|-------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|--|
|             | ANIMAL ID             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |  |
| 0           | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 |  |
| 7           | 7                     | 7 | 5 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 7        | 6 |  |
| 3           | 3                     | 0 | 6 | 0 | 3 | 3 | 3 | 4 | 6 | 2 | 2 | 2 | 2 | 3 | 3 | 9 | 2 | 2 | 1 | 2 | 8 | 2 | 3 | 5 |          |   |  |
| 1           | 1                     | 3 | 3 | 1 | 0 | 5 | 0 | 9 | 3 | 9 | 9 | 9 | 9 | 0 | 0 | 0 | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 9 |          |   |  |
| 0           | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 |  |
| 0           | 0                     | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 |  |
| 1           | 1                     | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1        | 1 |  |
| 2           | 2                     | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |   |  |
| 6           | 7                     | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |          |   |  |

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |

**NERVOUS SYSTEM**

|                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |       |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|-------|
| Brain            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +     | 50    |
| Compression      |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   | 3 | 3 3.0 |       |
| Hemorrhage       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 2 2.5 |
| Hydrocephalus    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |       | 1 2.0 |
| Necrosis         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 3.0 |
| Peripheral Nerve |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | + 4   |
| Spinal Cord      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | + 4   |

**RESPIRATORY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |        |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--------|
| Lung                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +      | 50     |
| Edema                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |        | 1 2.0  |
| Foreign Body                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1      |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 2 | 2 |   |   |   |   |   |   |   |   |        | 4 2.3  |
| Infiltration Cellular, Histiocyte | 1 | 1 |   | 1 | 1 |   | 1 | 1 | 1 |   |   |   |   | 1 | 1 |   |   |   |   |   |   |   | 1 |   |   | 25 1.2 |        |
| Inflammation, Chronic             |   |   | 1 |   |   |   | 1 |   |   |   |   | 2 |   | 2 | 1 |   |   |   |   |   |   |   | 1 |   |   |        | 17 1.2 |
| Alveolar Epithelium, Hyperplasia  |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |        | 3 1.0  |
| Nose                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +      | 50     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 50



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|------------------------------|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              |                  | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |
|                              |                  | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |
|                              |                  | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |
| <b>FISCHER 344 RATS MALE</b> | <b>ANIMAL ID</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>25000 PPM</b>             |                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                              |                  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|                              |                  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|                              |                  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                                       | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Intestine Large, Cecum<br>Edema                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 3 | + | + | + | + | + | 3 |
| Intestine Large, Colon                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum<br>Inflammation, Chronic | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum                        | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus                                |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X |   | X | X |   |   |
| Clear Cell Focus                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Degeneration, Cystic                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Eosinophilic Focus                              |   | X | X | X |   |   |   |   |   |   |   | X |   |   | X | X | X |   | X |   | X | X |   | X | X |   |
| Hepatodiaphragmatic Nodule                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infarct   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Mixed Cell               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 2 |   |
| Mixed Cell Focus                                | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |

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 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                           | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |
|---------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|                                       | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |
| 6                                     | 7         | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |   |                    |
| 3                                     | 3         | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |   |                    |
| 5                                     | 0         | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| FISCHER 344 RATS MALE<br>25000 PPM    | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
|                                       | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
|                                       | 1         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |                    |
|                                       | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |   |                    |
|                                       | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Necrosis, Focal                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Bile Duct, Hyperplasia                | 1         | 2 | 1 | 2 | 3 |   | 3 | 3 |   |   | 3 |   | 2 | 4 | 3 | 3 |   |   | 3 | 1 | 1 | 3 | 1 | 3 | 4 |                    |
| Centrilobular, Necrosis               |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Hepatocyte, Degeneration              | 2         | 2 | 3 |   |   |   |   |   |   |   |   |   | 3 |   | 1 |   | 1 | 2 |   | 3 | 2 |   | 3 |   |   |                    |
| Hepatocyte, Hypertrophy               | 3         | 2 | 4 | 1 |   |   |   |   | 4 |   |   | 1 | 4 |   | 3 |   | 3 |   |   | 2 |   | 4 | 2 |   |   |                    |
| Hepatocyte, Vacuolization Cytoplasmic |           |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Kupffer Cell, Pigmentation            |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Mesentery                             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Accessory Spleen                      |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Fat, Necrosis                         |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Pancreas                              | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                    |
| Atrophy                               |           |   |   |   | 3 |   |   |   | 2 | 1 |   |   |   | 2 | 3 | 2 | 3 |   |   |   |   |   |   | 1 |   |                    |
| Cyst                                  |           |   | X | X |   |   |   |   |   |   | X |   |   |   | X |   |   |   |   | X | X |   |   | X | X |                    |
| Acinus, Cytoplasmic Alteration        |           |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Acinus, Hyperplasia, Focal            |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Salivary Glands                       | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                    |
| Atrophy                               |           |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 1 |   |   |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Stomach, Forestomach                  | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                    |
| Edema                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Ulcer                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |                    |
| Epithelium, Hyperplasia               |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |                    |
| .....                                 |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| Stomach, Glandular                    | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |                    |
| Erosion                               |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |                    |
|                                       |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |                    |

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                    | 6 7 7 7 6 2 6 7 4 6 5 5 7 7 7 6 5 7 6 7 7 5 7 7 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>25000 PPM | 3 3 3 3 8 0 1 1 5 1 9 7 3 2 3 9 2 2 3 2 2 9 3 3 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 0 0 1 4 8 2 6 0 2 0 2 0 9 0 6 3 9 0 9 9 0 1 1 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                          | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                          | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                          | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

males  
(cont...)

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cardiomyopathy | 3 2 2 2 1 1 1 1 1 1 2 2 1 3 2 3 1 1 1 1 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thrombosis     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ENDOCRINE SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex                     | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Adrenal Cortical Nodule  | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                        | 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal                 | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hypertrophy, Focal                 | 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis                           | 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vacuolization Cytoplasmic, Focal   | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vacuolization Cytoplasmic, Diffuse | 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla                    | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                        | 1 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic                 | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland                  | + + + + + + M + + + + + I + + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland                    | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Angiectasis         | 3 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Cyst                | X X X 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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TDMS No. 99007 - 05  
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 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 6 | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 | 7 | 5 |
|             | 3 | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 | 0 | 0 |
|             | 5 | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 | 0 | 0 |

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| FISCHER 344 RATS MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| ANIMAL ID             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| 25000 PPM             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               |
|                       | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7               |
|                       | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   | males (cont...) |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pars Distalis, Hyperplasia, Focal |   |   |   |   | 1 | 2 |   |   |   | 3 |   |   |   | 1 |   |   |   |   |   | 2 |   |   |   |   |   |   |   |
| Pars Intermedia, Cyst             |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| C-cell, Hyperplasia               |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |
| Follicle, Cyst                    |   |   |   |   |   |   | X |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Follicular Cell, Hyperplasia      |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Granuloma Sperm       |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   | 2 |   | 2 | 2 |   | 2 |   |   | 2 |   |   | 2 |   | 2 |   |   | 2 |   | 2 |   |   |   | 2 |   | 3 |   |
| Prostate              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis           |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Acute   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic |   |   |   | 1 |   |   |   |   | 2 |   | 4 | 2 |   |   |   | 2 |   |   |   | 2 |   |   |   |   |   | 2 |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                    | 6 7 7 7 6 2 6 7 4 6 5 5 7 7 7 6 5 7 6 7 7 5 7 7 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>25000 PPM | 3 3 3 3 8 0 1 1 5 1 9 7 3 2 3 9 2 2 3 2 2 9 3 3 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 0 0 1 4 8 2 6 0 2 0 2 0 9 0 6 3 9 0 9 9 0 1 1 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                          | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | <b>males (cont...)</b>                            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Seminal Vesicle  
 Inflammation, Chronic +

Testes  
 Germinal Epithelium, Atrophy + + + + + + + 1 + + + + + + + + + + + + + + + + + + 2  
 Interstitial Cell, Hyperplasia 1 2 4 2

**HEMATOPOIETIC SYSTEM**

Bone Marrow  
 Hyperplasia +  
 Myelofibrosis 2 3 3 3 4 3

Lymph Node  
 Mediastinal, Ectasia +  
 Mediastinal, Hemorrhage +  
 Mediastinal, Hyperplasia, Lymphoid 3  
 Mediastinal, Pigmentation  
 Pancreatic, Ectasia  
 Pancreatic, Hemorrhage  
 Pancreatic, Hyperplasia, Lymphoid

Lymph Node, Mandibular M

Lymph Node, Mesenteric  
 Atrophy +  
 Ectasia  
 Hemorrhage

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |
|------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS MALE<br>25000 PPM |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |
| ANIMAL ID                          |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |   |
|                                    |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |   |
|                                    |  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |   |   |
|                                    |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males  
(cont...)

|                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hyperplasia, Lymphoid            | 2 | 2 |   | 2 |   | 3 |   |   | 2 |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |
| Spleen                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Fibrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hematopoietic Cell Proliferation |   |   |   |   |   |   | 1 |   | 1 |   | 1 | 1 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |
| Hemorrhage                       |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |
| Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thymus                           | + | + | + | + | + | + |   | 1 | + | + | + | + | + | + | + | + |   | M | + | + | + | + | + | + |   |
| Atrophy                          |   |   |   | 3 |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia               |   |   |   | 1 |   | 2 |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperkeratosis            |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**MUSCULOSKELETAL SYSTEM**

|          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Fracture |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 57

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

|  | DAY ON TEST            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|  | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | 6                      | 7 | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |
|  | 3                      | 3 | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |
|  | 5                      | 0 | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |
| <b>FISCHER 344 RATS MALE</b><br><b>25000 PPM</b> | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | 0                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | 1                      | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|  | 5                      | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
|  | 1                      | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
|  | <b>males (cont...)</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Skeletal Muscle Atrophy + 1 +

**NERVOUS SYSTEM**

Brain +  
 Compression 2  
 Gliosis  
 Hemorrhage  
 Metaplasia, Lipocyte  
 Peripheral Nerve +  
 Spinal Cord

**RESPIRATORY SYSTEM**

Lung +  
 Hemorrhage 2 2  
 Infiltration Cellular, Histiocyte 3 1 1 1 3 1 1 1 4  
 Inflammation, Chronic 1  
 Metaplasia, Osseous  
 Alveolar Epithelium, Hyperplasia 1 1 2 2 2  
 Nose +  
 Foreign Body X X X X X  
 Inflammation, Chronic 1 1 1

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 58

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |
| 6           | 7         | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 | 0 |                    |
| 3           | 3         | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 | 0 |                    |
| 5           | 0         | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 | 0 |                    |

**FISCHER 344 RATS MALE**  
**25000 PPM**

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Respiratory Epithelium, Hyperplasia | 1 |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Focal   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney                                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst  |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hydronephrosis                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infarct                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nephropathy                                 | 1 | 3 | 2 | 1 | 2 |   | 2 | 2 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 3 | 1 | 3 | 2 | 1 |   |
| Renal Tubule, Accumulation, Hyaline Droplet |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Mineralization                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |
|------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
|                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |
| 6                            | 7         | 7 | 7 | 6 | 2 | 6 | 7 | 4 | 6 | 5 | 5 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 5 |   |                    |
| 3                            | 3         | 3 | 3 | 8 | 0 | 1 | 1 | 5 | 1 | 9 | 7 | 3 | 2 | 3 | 9 | 2 | 2 | 3 | 2 | 2 | 9 | 3 | 3 | 0 |   |                    |
| 5                            | 0         | 0 | 1 | 4 | 8 | 2 | 6 | 0 | 2 | 0 | 2 | 0 | 9 | 0 | 6 | 3 | 9 | 0 | 9 | 9 | 0 | 1 | 1 | 9 |   |                    |
| .....                        |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                    |
| <b>FISCHER 344 RATS MALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
| <b>25000 PPM</b>             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                    |
|                              | 1         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |                    |
|                              | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |                    |
|                              | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                    |

Hemorrhage 4  
 Inflammation, Acute 3

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

Page 60

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                     | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |          |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----------|
|   | 7 7 7 6 5 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 7 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |
|   | 1 1 3 3 7 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | * TOTALS |
|   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |          |
|   | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1        |          |
|   | 7   | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9        |          |
|   | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |          |

**ALIMENTARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |                  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|------------------|
| Esophagus                                       | + | M | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 47               |
| Intestine Large, Cecum<br>Edema                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50<br>2 3.0      |
| Intestine Large, Colon                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50               |
| Intestine Large, Rectum                         | + | I | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 49               |
| Intestine Small, Duodenum                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | +  | 49               |
| Intestine Small, Ileum<br>Inflammation, Chronic | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 48<br>2<br>1 2.0 |
| Intestine Small, Jejunum                        | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 48               |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +  | 50               |
| Basophilic Focus                                | X |   |   |   | X |   | X | X |   |   |   |   |   |   |   |   |   | X | X | X | X |   | X | X | 13 |                  |
| Clear Cell Focus                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X |   |    | 2                |
| Degeneration, Cystic                            | 1 |   |   | 1 |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |    | 7 1.1            |
| Eosinophilic Focus                              | X |   | X |   |   |   | X | X | X | X |   |   | X | X |   | X |   | X | X | X | X | X | X | X | X  | 28               |
| Hepatodiaphragmatic Nodule                      |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 2                |
| Infarct   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 4.0            |
| Infiltration Cellular, Mixed Cell               |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   | 1 | 3 |   |   |   |   | 2 |   |    | 6 2.0            |
| Mixed Cell Focus                                |   | X |   | X |   | X |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | X |   |    | 7                |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                           |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |          |
|---------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|----------|
| ANIMAL ID                             |  | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7     |          |
| FISCHER 344 RATS MALE<br>25000 PPM    |  | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3     |          |
|                                       |  | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1     |          |
|                                       |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |          |
|                                       |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0     |          |
|                                       |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2     |          |
|                                       |  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9     |          |
|                                       |  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8     | * TOTALS |
| Necrosis, Focal                       |  |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   | 1 |   |   |   |   |   |   | 2 1.0 |          |
| Bile Duct, Hyperplasia                |  | 3 | 2 | 4 | 4 |   | 1 |   | 3 | 2 | 3 | 1 | 3 | 3 |   | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 3     | 39 2.2   |
| Centrilobular, Necrosis               |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |       | 1 1.0    |
| Hepatocyte, Degeneration              |  | 2 | 3 |   |   |   | 2 |   |   | 3 |   |   |   |   |   | 2 |   |   | 3 |   | 2 |   | 2 | 2     | 19 2.3   |
| Hepatocyte, Hypertrophy               |  | 2 | 4 |   |   |   | 3 | 2 |   | 3 |   | 3 |   |   | 2 |   |   | 1 | 3 | 2 | 2 | 3 | 3 | 3     | 27 2.6   |
| Hepatocyte, Vacuolization Cytoplasmic |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 4.0    |
| Kupffer Cell, Pigmentation            |  |   |   |   | 3 |   |   |   |   |   |   | 2 | 2 |   |   |   |   |   |   |   |   |   |   |       | 3 2.3    |
| Mesentery                             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 7     |          |
| Accessory Spleen                      |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |       | 1        |
| Fat, Necrosis                         |  |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |       | 3 3.0    |
| Pancreas                              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50    |          |
| Atrophy                               |  | 1 |   |   |   |   | 1 |   | 1 | 1 |   |   |   |   | 1 | 1 |   | 2 |   | 3 |   |   | 2 | 3     | 18 1.8   |
| Cyst                                  |  |   | X |   |   |   |   |   |   | X |   |   |   |   | X |   |   | X |   |   | X | X |   |       | 14       |
| Acinus, Cytoplasmic Alteration        |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 3.0    |
| Acinus, Hyperplasia, Focal            |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 3.0    |
| Salivary Glands                       |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50    |          |
| Atrophy                               |  |   | 1 |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |       | 6 1.2    |
| Stomach, Forestomach                  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50    |          |
| Edema                                 |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |       | 1 2.0    |
| Ulcer                                 |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       | 1 3.0    |
| Epithelium, Hyperplasia               |  | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |       | 3 1.7    |
| Stomach, Glandular                    |  |   |   |   |   | A |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 49    |          |
| Erosion                               |  |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |       | 3 2.0    |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                     | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 1 3 3 7 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                                       | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>* TOTALS</b>                                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |               |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---------------|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |
| Cardiomyopathy | 2 2 1 2 3 3 1 1 1 1 2 3 2 2 2 2 1 1 2 3         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>36 1.8</b> |
| Thrombosis     | 4   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 4.0</b>  |

**ENDOCRINE SYSTEM**

|                                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |               |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---------------|
| Adrenal Cortex                     | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |
| Accessory Adrenal Cortical Nodule  | 3         |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>19 3.0</b> |
| Hyperplasia                        | 2 1 1 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>7 1.4</b>  |
| Hyperplasia, Focal                 | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>2 2.0</b>  |
| Hypertrophy, Focal                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 2.0</b>  |
| Necrosis                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 3.0</b>  |
| Vacuolization Cytoplasmic, Focal   | 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>4 1.3</b>  |
| Vacuolization Cytoplasmic, Diffuse |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 3.0</b>  |
| Adrenal Medulla                    | + + + + M + + + + + + + I + + + + + + + + + + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>48</b>     |
| Hyperplasia                        | 1 1 2 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>9 1.2</b>  |
| Islets, Pancreatic                 | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |
| Parathyroid Gland                  | + + + + + + + + + + + + + M + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>47</b>     |
| Pituitary Gland                    | +     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |
| Pars Distalis, Angiectasis         | 1 2 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>5 2.0</b>  |
| Pars Distalis, Cyst                | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>4</b>      |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 99007 - 05  
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**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            |                 |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|-----------------|
|                                   | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7            |                 |
|                                   | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3            |                 |
|                                   | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1 | 1            |                 |
| <b>FISCHER 344 RATS MALE</b>      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            |                 |
| <b>25000 PPM</b>                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            |                 |
| ANIMAL ID                         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2            |                 |
|                                   | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0            |                 |
|                                   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9            | 0               |
|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              | <b>* TOTALS</b> |
| Pars Distalis, Hyperplasia, Focal |   |   |   |   | 2 | 3 |   | 2 | 3 |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |              | <b>10 2.0</b>   |
| Pars Intermedia, Cyst             |   |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   |   | X |   |   |   | X |   | <b>5</b>     |                 |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>    |                 |
| Ultimobranchial Cyst              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>     |                 |
| C-cell, Hyperplasia               |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | <b>6 1.7</b> |                 |
| Follicle, Cyst                    |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>     |                 |
| Follicular Cell, Hyperplasia      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 2.0</b> |                 |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |               |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Epididymis            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +         | <b>50</b>     |
| Granuloma Sperm       |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2 2.5</b>  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2 2.0</b>  |
| Preputial Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 2.0</b>  |
| Inflammation, Chronic |   |   |   |   | 2 |   | 2 |   | 2 | 3 |   |   | 2 |   | 2 | 2 |   |   | 2 |   |   |   |   |           | <b>20 2.1</b> |
| Prostate              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |               |
| Angiectasis           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 3.0</b>  |
| Inflammation, Acute   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1 3.0</b>  |
| Inflammation, Chronic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>10 2.4</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                     | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|   | 1 1 3 3 7 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|   | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                 |
|   | 7   | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |                 |
|   | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | <b>* TOTALS</b> |

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |                              |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------------------------|
| Seminal Vesicle<br>Inflammation, Chronic                                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> | <b>1 3.0</b>                 |
| Testes<br>Germinal Epithelium, Atrophy<br>Interstitial Cell, Hyperplasia | + | + | + | + | + | + | 2 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> | <b>8 2.6</b><br><b>3 1.0</b> |

**HEMATOPOIETIC SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--|
| Bone Marrow<br>Hyperplasia<br>Myelofibrosis  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> | <b>8 3.0</b><br><b>3 3.0</b>   |
| Lymph Node<br>Mediastinal, Ectasia<br>Mediastinal, Hemorrhage<br>Mediastinal, Hyperplasia, Lymphoid<br>Mediastinal, Pigmentation<br>Pancreatic, Ectasia<br>Pancreatic, Hemorrhage<br>Pancreatic, Hyperplasia, Lymphoid |   |   | + |   |   |   |   | + | + | + |   |   | + |   | + |   |   |   |   |   |   |   |   | + | <b>19</b> | <b>1 3.0</b><br><b>1 2.0</b><br><b>3 2.7</b><br><b>1 2.0</b><br><b>1 3.0</b><br><b>1 1.0</b><br><b>1 2.0</b> |
| Lymph Node, Mandibular   | M | M | M | M | M | M | M | M | M | M | + | M | M | M | M | M | + | M | M | M | M | M | M | M | <b>2</b>  |  |
| Lymph Node, Mesenteric<br>Atrophy<br>Ectasia<br>Hemorrhage   | + | + | + | + | + | + | + | + | + | + | + | 2 | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> | <b>1 2.0</b><br><b>2 3.0</b><br><b>1 1.0</b>   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                              | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7               |
|                              | 3 | 3 | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3               |
|                              | 1 | 1 | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1               |
| <b>FISCHER 344 RATS MALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| <b>25000 PPM</b>             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| ANIMAL ID                    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2               |
|                              | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |
|                              | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | 0 | <b>* TOTALS</b> |

|                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |  |   |   |   |   |            |            |            |            |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-----------|--|---|---|---|---|------------|------------|------------|------------|
| Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |           | 2         |  |   |   | 2 |   |            |            | 8          | <b>2.1</b> |
| Spleen                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +         | <b>50</b> |  |   |   |   |   |            |            |            |            |
| Fibrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3         |           |  |   | 2 |   |   |            | 2          | <b>2.5</b> |            |
| Hematopoietic Cell Proliferation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |           | 1         |  |   |   | 3 |   |            |            | 2          | <b>1.6</b> |
| Hemorrhage                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |  | 3 |   |   |   | 2          | <b>3.0</b> |            |            |
| Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |  |   |   |   | 2 | <b>2.0</b> |            |            |            |
| Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |  |   |   |   | 1 | <b>4.0</b> |            |            |            |
| Thymus                           | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>47</b> |           |  |   |   |   |   |            |            |            |            |
| Atrophy                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |  |   |   |   | 2 | <b>2.5</b> |            |            |            |

**INTEGUMENTARY SYSTEM**

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |   |  |  |  |   |            |   |            |            |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--|---|--|--|--|---|------------|---|------------|------------|
| Mammary Gland             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |  |   |  |  |  |   |            |   |            |            |
| Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 2 | 3 |   |           |  | 2 |  |  |  | 8 | <b>1.9</b> |   |            |            |
| Skin                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |  |   |  |  |  |   |            |   |            |            |
| Cyst Epithelial Inclusion |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |   |  |  |  |   |            | X | <b>2</b>   |            |
| Hyperkeratosis            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |   |  |  |  |   |            | 1 | <b>3.0</b> |            |
| Ulcer                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |           |  |   |  |  |  |   |            |   | 1          | <b>3.0</b> |

**MUSCULOSKELETAL SYSTEM**

|          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |  |  |  |   |  |  |  |          |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--|--|--|--|---|--|--|--|----------|
| Bone     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |  |  |  |  |   |  |  |  |          |
| Fracture |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |  |  |  |  | X |  |  |  | <b>1</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                     | 0     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|   | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7 7   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| FISCHER 344 RATS MALE<br>25000 PPM<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3 3   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
|   | 1 1 3 3 7 0 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
|   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | * TOTALS |
|   | 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|   | 1   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |          |
|   | 7   | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |          |
|   | 6   | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |          |

Skeletal Muscle Atrophy + 3 1 1.0

**NERVOUS SYSTEM**

|                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |   |   |       |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|---|---|-------|
| Brain                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |   |   |       |
| Compression          | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3  | 3 | 3 | 4 2.5 |
| Gliosis              |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3  |   |   | 1 3.0 |
| Hemorrhage           | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |   |   | 1 3.0 |
| Metaplasia, Lipocyte |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | 2 |   | 1 2.0 |
| Peripheral Nerve     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | + | + | 3     |
| Spinal Cord          |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | + | + | 2     |

**RESPIRATORY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |   |   |        |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|---|---|--------|
| Lung                              | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |   |   |        |
| Hemorrhage                        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 4  | 2 |   | 4 2.5  |
| Infiltration Cellular, Histiocyte | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  | 1 | 1 | 24 1.4 |
| Inflammation, Chronic             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1  |   | 1 | 3 1.0  |
| Metaplasia, Osseous               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | 1 |   | 1 1.0  |
| Alveolar Epithelium, Hyperplasia  | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | 1 | 2 | 8 1.5  |
| Nose                              | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 50 |   |   |        |
| Foreign Body                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    | X |   | 6      |
| Inflammation, Chronic             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |    |   |   | 3 1.0  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                        | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                    | 7 7 7 6 5 7 7 7 7 7 7 6 6 4 6 7 4 7 6 7 7 7 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS MALE<br>ANIMAL ID | 3 3 2 5 4 3 3 3 3 3 0 2 7 5 5 2 7 1 8 2 3 3 3 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 1 3 3 7 0 0 0 0 0 0 3 7 4 1 6 9 8 1 8 9 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                          | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                          | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 1 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                    | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>* TOTALS</b>                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

|                                     |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |              |
|-------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Respiratory Epithelium, Hyperplasia |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>3 1.0</b> |
| Trachea                             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>    |

**SPECIAL SENSES SYSTEM**

|                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |              |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Eye                  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>    |
| Cataract             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 3.0</b> |
| Retina, Degeneration | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>2 2.0</b> |
| Harderian Gland      | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>    |
| Hyperplasia, Focal   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 1.0</b> |

**URINARY SYSTEM**

|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |               |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---------------|
| Kidney                                      | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |
| Cyst  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1</b>      |
| Hydronephrosis                              |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 2.0</b>  |
| Infarct                                     | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>2 2.0</b>  |
| Nephropathy                                 | 2 3 1 1 1 2 1 3 3 2 1 1 1 1 1 2 1 1 2 2 1 3 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>49 1.7</b> |
| Renal Tubule, Accumulation, Hyaline Droplet | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 3.0</b>  |
| Renal Tubule, Mineralization                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1 2.0</b>  |
| Renal Tubule, Necrosis                      | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>2 2.0</b>  |
| Renal Tubule, Pigmentation                  | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>4 2.3</b>  |
| Urinary Bladder                             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>50</b>     |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 68

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              | * TOTALS |
|------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|----------|
|                              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            |          |
| 7                            | 7         | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 4 | 6 | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7            | 0        |
| 3                            | 3         | 2 | 5 | 4 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 7 | 5 | 5 | 2 | 7 | 1 | 8 | 2 | 3 | 3 | 3 | 3 | 3            | 0        |
| 1                            | 1         | 3 | 3 | 7 | 0 | 0 | 0 | 0 | 0 | 3 | 7 | 4 | 1 | 6 | 9 | 8 | 1 | 8 | 9 | 1 | 1 | 1 | 1 | 1            | 0        |
| .....                        |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |          |
| <b>FISCHER 344 RATS MALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            | 0        |
| <b>25000 PPM</b>             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0            | 0        |
|                              | 1         | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1            | 2        |
|                              | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9            | 0        |
|                              | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9            | 0        |
|                              |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 4.0</b> |          |
| Hemorrhage                   |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b> |          |
| Inflammation, Acute          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |          |

\*\*\* END OF MALE DATA \*\*\*

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                |  | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|                                |  | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                |  | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 |
| <b>FISCHER 344 RATS FEMALE</b> |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>0 PPM</b>                   |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
|                                |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |

females  
(cont...)

ALIMENTARY SYSTEM

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                         | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum<br>Edema   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | A | A | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus                  | X | X | X | X | X | X | X | X |   | X | X |   | X | X | X | X | X | X | X | X | X | X | X |
| Clear Cell Focus                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Eosinophilic Focus                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hematopoietic Cell Proliferation  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   |   | 2 | 1 |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Mixed Cell Focus                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Necrosis, Focal                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Bile Duct, Hyperplasia            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|             | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|             | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1 |

---

| FISCHER 344 RATS FEMALE<br>0 PPM | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|----------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                  |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                  |           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |

females  
(cont...)

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Centrilobular, Necrosis<br>Hepatocyte, Degeneration<br>Hepatocyte, Hypertrophy<br>Hepatocyte, Vacuolization Cytoplasmic<br>Kupffer Cell, Pigmentation | 2 |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |
| Mesentery<br>Fat, Necrosis  | + |   |   |   |   | + | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
|   | 3 |   |   |   |   | 3 | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |
| Pancreas<br>Atrophy<br>Cyst<br>Acinus, Cytoplasmic Alteration   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
|   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |
| Salivary Glands<br>Atrophy  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
|   |   |   |   | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach<br>Ulcer   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Stomach, Glandular<br>Erosion   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
|   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tongue  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

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 + .. Tissue examined microscopically  
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 M .. Missing tissue  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 71

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST   | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|   | 7 7 7 7 7 7 7 7 6 5 7 6 7 7 7 6 7 7 7 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>0 PPM ANIMAL ID            | 3 3 3 3 1 3 3 3 9 3 3 1 3 3 3 6 3 3 3 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 6 6 6 6 9 1 1 1 0 7 2 1 2 2 2 6 3 3 3 3 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 0 PPM<br>ANIMAL ID                                    | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cardiomyopathy<br>Inflammation, Chronic<br>Thrombosis | 1 1 1 2 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

females  
(cont...)

**ENDOCRINE SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex                    | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Adrenal Cortical Nodule |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Degeneration, Fatty               | 1 3 2 1 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hematopoietic Cell Proliferation  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal                | 1 1 2 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hypertrophy, Focal                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis                          |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla                   | + + + + M +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic                | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland                 | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland                   | +       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pigmentation                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Angiectasis        | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Cyst               | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Hyperplasia, Focal | 2 2 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Intermedia, Angiectasis      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Intermedia, Cyst             | X X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 72



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |
| 3                              | 3         | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
| 6                              | 6         | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1 |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
| <b>0 PPM</b>                   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |                      |
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |   |                      |

Thyroid Gland  
 C-cell, Hyperplasia

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   | 1 |   |   |   |   |   | 1 |   |   |   |   | 1 |   |   |   |   | 1 | 2 | 2 | 1 | 1 |   | 1 |   |

**GENERAL BODY SYSTEM**

Tissue NOS

**GENITAL SYSTEM**

Clitoral Gland  
 Cyst  
 Hyperplasia  
 Hyperplasia, Focal

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Ovary  
 Cyst

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   | X |   |   |   |   | X | X |   |   |   |   |   |   |   |   |   | X |   | X |   |   |   |   |

Uterus  
 Hemorrhage  
 Hyperplasia, Cystic

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   | 1 | 1 |   | 2 |   |   | 2 |   |

Vagina

+

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|   | 7 7 7 7 7 7 7 7 6 5 7 6 7 7 7 6 7 7 7 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>0 PPM              | 3 3 3 3 1 3 3 3 9 3 3 1 3 3 3 6 3 3 3 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 6 6 6 6 9 1 1 1 0 7 2 1 2 2 2 6 3 3 3 3 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                                     | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | females (cont...)                                 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bone Marrow                                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                                   | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Myelofibrosis                                 | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node                                    | + + + + +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                                    | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pigmentation                                  | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hematopoietic Cell Proliferation |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hemorrhage                       | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Hyperplasia, Lymphoid            | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mediastinal, Pigmentation                     | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pancreatic, Hemorrhage                        | 3   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mandibular                        | M + M M + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lymph Node, Mesenteric                        | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                                    | 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Lymphoid                         | 2 2 2 2 2 3 2 2 2 3 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Spleen  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Spleen                              | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hematopoietic Cell Proliferation              | 2 2 3 1 2 2 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Thymus  | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cyst  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |
| 3                              | 3         | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
| 6                              | 6         | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1 |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
| <b>0 PPM</b>                   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                      |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |                      |
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

Mammary Gland  
 Hyperplasia

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 1 |   | 3 | 3 | 1 | 4 | 4 | 3 | 4 | 3 |

Skin  
 Hemorrhage  
 Hyperkeratosis  
 Ulcer  
 Epidermis, Hyperplasia

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**MUSCULOSKELETAL SYSTEM**

Bone  
 Fracture

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |

**NERVOUS SYSTEM**

Brain  
 Compression  
 Gliosis  
 Hemorrhage  
 Necrosis

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 2 |   |   |   | 4 |   |   |   | 4 | 4 |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |
|   |   |   |   | 2 |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Peripheral Nerve

Spinal Cord

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 75

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                 | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                          |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------------|
|   | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7                        |
|   | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                        |
|   | 6 | 6 | 6 | 6 | 9 | 1 | 1 | 1 | 0 | 7 | 2 | 1 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 1 | 1                        |
| <b>FISCHER 344 RATS FEMALE</b><br>ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                          |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                          |
|   | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                          |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |                          |
|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5                        |
| <b>0 PPM</b>                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>females (cont...)</b> |

**RESPIRATORY SYSTEM**

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Edema                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hemorrhage                          |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Lymphoid               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Infiltration Cellular, Histiocyte   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   | 1 |   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |   |
| Inflammation, Chronic               | 1 |   | 1 |   | 1 | 1 |   | 1 |   | 2 |   | 1 |   | 1 | 1 | 1 | 1 |   |   |   |   |   |   |   |
| Alveolar Epithelium, Hyperplasia    | 1 | 1 |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   | 2 | 3 |   |   |   |   | 1 |   |
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Foreign Body                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |
| Harderian Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Focal   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|   | 7 7 7 7 7 7 7 7 6 5 7 6 7 7 7 6 7 7 7 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>0 PPM<br>ANIMAL ID | 3 3 3 3 1 3 3 3 9 3 3 1 3 3 3 6 3 3 3 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 6 6 6 6 9 1 1 1 0 7 2 1 2 2 2 6 3 3 3 3 1 1 1 1 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|   | <b>females (cont...)</b>                          |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**URINARY SYSTEM**

|   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney                                      | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cyst  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inflammation, Suppurative                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Metaplasia, Osseous                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Nephropathy                                 | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Papilla, Necrosis                           |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Renal Tubule, Accumulation, Hyaline Droplet |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Renal Tubule, Necrosis                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Renal Tubule, Pigmentation                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Transitional Epithelium, Hyperplasia        | 2   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Urinary Bladder                             | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Edema                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Transitional Epithelium, Hyperplasia        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 2) Mild 4) Marked  
 Page 77









TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
|                                | 7           | 4 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                 |
|                                | 3           | 0 | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 |                 |
|                                | 3           | 4 | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 |                 |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| <b>0 PPM</b>                   | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                 |
| ANIMAL ID                      | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                 |
|                                | 2           | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |                 |
|                                | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | <b>* TOTALS</b> |

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Thyroid Gland       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |
| C-cell, Hyperplasia | 2 |   |   |   |   |   | 2 | 1 |   |   | 1 |   |   |   |   | 1 |   |   | 1 |   | 1 |   | 3 |   | <b>17 1.4</b> |

**GENERAL BODY SYSTEM**

|            |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| Tissue NOS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | <b>1</b> |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|

**GENITAL SYSTEM**

|                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Clitoral Gland      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>    |
| Cyst                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>     |
| Hyperplasia         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 2.0</b> |
| Hyperplasia, Focal  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | <b>1 2.0</b> |
| Ovary               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>    |
| Cyst                |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   | X | <b>8</b>     |
| Uterus              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>    |
| Hemorrhage          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1 3.0</b> |
| Hyperplasia, Cystic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 | 4 |   |   |   |   | 3 |   |   | <b>8 2.0</b> |
| Vagina              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>     |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05  
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 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                   | 0 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |     |     |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-----|-----|
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0   |     |
| FISCHER 344 RATS FEMALE                       | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |     |     |
| 0 PPM   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |     |     |
| ANIMAL ID                                     | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |     |     |
|   | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |     |     |
|   | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |     |     |
| Bone Marrow                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |     |     |
| Hyperplasia                                   |   | 4 |   | 2 |   |   |   |   | 4 |   |   |   | 3 | 2 |   | 3 | 3 |   |   |   | 3 |   |   |   | 10       | 2.8 |     |
| Myelofibrosis                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   | 1        | 3.0 |     |
| Lymph Node                                    | + |   | + |   |   |   |   |   |   |   |   |   |   |   | + |   | + |   |   |   |   |   |   | + | 9        |     |     |
| Hemorrhage                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1   | 3.0 |
| Pigmentation                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1   | 3.0 |
| Mediastinal, Hematopoietic Cell Proliferation |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1   | 2.0 |
| Mediastinal, Hemorrhage                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 5   | 2.4 |
| Mediastinal, Hyperplasia, Lymphoid            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 4   | 1.8 |
| Mediastinal, Pigmentation                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 2   | 2.0 |
| Pancreatic, Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 2   | 3.0 |
| Lymph Node, Mandibular                        | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M        | 2   |     |
| Lymph Node, Mesenteric                        | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 49  |     |
| Hemorrhage                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 3   | 1.7 |
| Hyperplasia, Lymphoid                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 15  | 2.2 |
| Spleen  | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 49  |     |
| Accessory Spleen                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 2   |     |
| Hematopoietic Cell Proliferation              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 37  | 2.4 |
| Thymus  | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 49  |     |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1   |     |

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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TDMS No. 99007 - 05  
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 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7                              | 4         | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0        |
| 3                              | 0         | 1 | 2 | 2 | 3 | 3 | 6 | 3 | 2 | 7 | 8 | 8 | 7 | 0 | 1 | 9 | 3 | 3 | 0 | 3 | 1 | 3 | 3 | 3 | 0        |
| 3                              | 4         | 1 | 7 | 7 | 1 | 1 | 3 | 1 | 3 | 5 | 9 | 2 | 5 | 9 | 6 | 6 | 6 | 6 | 3 | 3 | 1 | 3 | 3 | 3 | 0        |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>0 PPM</b>                   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |
|                                | 2         | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|---------|
| Kidney                                      | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | +      | 49      |
| Cyst  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1       |
| Inflammation, Suppurative                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1 3.0   |
| Metaplasia, Osseous                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1 1.0   |
| Nephropathy                                 |   |   |   | 1 |   | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 |   | 1 |   | 1 | 1 |   | 1 | 1 | 1 | 1 | 36 1.0 |         |
| Papilla, Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1 3.0   |
| Renal Tubule, Accumulation, Hyaline Droplet | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 3.0  |         |
| Renal Tubule, Necrosis                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1 3.0   |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 1 2.0   |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 2 2.5   |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +      | 50      |
| Edema                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 2 1 2.0 |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        | 2 1 2.0 |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 85

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                      | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 6 7 5 7 7 7 6 7 7   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>3000 PPM<br>ANIMAL ID | 3 3 3 3 3 3 3 3 6 3 3 3 3 3 3 0 2 3 8 3 3 3 4 3 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 2 2 2 2 2 1 1 1 8 1 3 3 3 3 3 9 7 6 9 6 1 1 2 1 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**females (cont...)**

**ALIMENTARY SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus                         | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Cecum            | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Colon            | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Large, Rectum           | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Duodenum         | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Ileum            | + + + + + + + + + + + + M + + + + + + + + + + + + + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Intestine Small, Jejunum          | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Liver                             | +   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basophilic Focus                  | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Clear Cell Focus                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Eosinophilic Focus                | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hemorrhage                        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hepatodiaphragmatic Nodule        | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infiltration Cellular, Mixed Cell | 4 1 3 1 3 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mixed Cell Focus                  | X   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Bile Duct, Hyperplasia            | 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hepatocyte, Degeneration          | 1 1   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 l .. Insufficient tissue

M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females (cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
|             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
| 7           | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 |   |                   |
| 3           | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 |   |                   |
| 2           | 2         | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 |   |                   |
| 0           | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                   |
| 0           | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                   |
| 2           | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |                   |
| 5           | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |   |                   |
| 1           | 2         | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |                   |

|                                       |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
|---------------------------------------|---|---|---|---|---|--|---|--|---|--|--|--|--|--|---|---|--|---|--|--|--|---|--|---|
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 |   |  |   |  | 1 |  |  |  |  |  | 2 | 2 |  | 2 |  |  |  |   |  |   |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |  |   |  |   |  |  |  |  |  | 2 |   |  |   |  |  |  |   |  |   |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Mesentery                             |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Accessory Spleen                      |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Fat, Necrosis                         |   |   |   |   |   |  |   |  |   |  |  |  |  |  | 4 | 3 |  |   |  |  |  |   |  | 2 |
| Pancreas                              |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Atrophy                               |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Cyst                                  | X |   |   |   | X |  | X |  |   |  |  |  |  |  | 3 |   |  | 2 |  |  |  | X |  | X |
| Acinus, Cytoplasmic Alteration        |   |   |   |   |   |  |   |  |   |  |  |  |  |  | 3 |   |  |   |  |  |  |   |  |   |
| Acinus, Hyperplasia, Focal            |   |   |   |   |   |  |   |  |   |  |  |  |  |  | 2 |   |  |   |  |  |  |   |  |   |
| Salivary Glands                       |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Stomach, Forestomach                  |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Edema                                 |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Ulcer                                 |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Epithelium, Hyperplasia               |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Stomach, Glandular                    |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Edema                                 |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |
| Erosion                               |   |   |   |   |   |  |   |  |   |  |  |  |  |  |   |   |  |   |  |  |  |   |  |   |

**CARDIOVASCULAR SYSTEM**

|       |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                       | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females (cont...) |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
| 7   | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 |   |                   |
| 3   | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |                   |
| 2   | 2         | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |                   |
| <hr/>   |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                   |
| <b>FISCHER 344 RATS FEMALE</b><br><b>3000 PPM</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                   |
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                   |
|   | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |                   |
|   | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |   |                   |
|   | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                   |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thyroid Gland                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia          | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   | 1 |   |   |   |
| Follicle, Cyst               |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Follicular Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**  
 NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hyperplasia, Focal    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 3 | 2 |   |   |   |   |   | 2 |   |   |   |   |
| Ovary                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Cyst                  |   |   |   | X |   |   |   |   |   |   |   | X |   |   | X |   |   |   |   | X |   |   |   |   |   |
| Uterus                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Decidual Reaction     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |
| Hyperplasia, Cystic   |   |   | 4 | 1 | 2 |   |   |   |   | 4 |   |   |   | 1 | 2 |   |   |   |   |   | 2 |   |   |   |   |
| Vagina                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | + |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

|                                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST                        |  | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 |   |
|                                    |  | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 |   |
|                                    |  | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 |   |
|                                    |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| FISCHER 344 RATS FEMALE            |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                          |  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| 3000 PPM                           |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                    |  | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |   |
|                                    |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |   |
|                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Bone Marrow                        |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |
| Hyperplasia                        |  |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |
| Infiltration Cellular, Histiocyte  |  |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |
| Myelofibrosis                      |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node                         |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Hemorrhage            |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Hyperplasia, Lymphoid |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mediastinal, Pigmentation          |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreatic, Hemorrhage             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreatic, Pigmentation           |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mandibular             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ectasia                            |  | M | M | M | + | M | M | M | M | M | M | M | M | M | M | + | M | M | M | M | M | M | + | M |   |
| Hyperplasia, Lymphoid              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymph Node, Mesenteric             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hemorrhage                         |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Hyperplasia, Lymphoid              |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Spleen                             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fibrosis                           |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| Hematopoietic Cell Proliferation   |  | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 2 |   | 3 | 3 |   | 3 | 1 | 3 | 3 |   | 3 | 3 | 2 | 2 |   |   |   |
|                                    |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Thymus                             |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Atrophy                            |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

females  
(cont...)

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 90

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                        |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------------|
|  |           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 0                        |
|  |           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |   |                          |
|  |           | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |   |                          |
| <b>FISCHER 344 RATS FEMALE</b><br>3000 PPM | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                        |
|  |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                        |
|  |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2                        |
|  |           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7                        |
|  |           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   | <b>females (cont...)</b> |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland<br>Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                              |   |   |   | 1 | 4 | 2 | 2 | 2 | 1 |   | 2 | 3 | 4 | 1 | 1 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 3 | 4 | 4 |   |
| Skin                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**MUSCULOSKELETAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone<br>Osteopetrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**NERVOUS SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain<br>Compression | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                      |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   | 4 |   | 4 |   |   |   |   | 4 | 3 | 4 |
| Peripheral Nerve     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Spinal Cord          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**RESPIRATORY SYSTEM**

|               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung<br>Edema | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body  |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 91  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 |
|             | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |   |
|             | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |   |

---

| FISCHER 344 RATS FEMALE<br>3000 PPM | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                     | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                     | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |
|                                     | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |

females  
(cont...)

|  |   |  |   |  |   |   |   |   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|--|---|--|---|---|---|---|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Infiltration Cellular, Histiocyte Inflammation, Chronic Metaplasia, Osseous Alveolar Epithelium, Hyperplasia Serosa, Hyperplasia | 1 |  | 1 |  |   | 1 | 1 | 1 |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|  |   |  | 1 |  | 1 | 2 |   | 1 |  | 1 | 1 |   | 1 |   | 1 |   | 1 |   | 1 |   | 1 |   | 1 |   | 1 |
|  |   |  |   |  |   |   |   |   |  |   |   |   |   |   |   |   | 3 |   | 1 |   |   |   |   |   |   |

|                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nose Foreign Body | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**SPECIAL SENSES SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye Cataract Retina, Degeneration | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

**URINARY SYSTEM**

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney Infarct Infiltration Cellular, Mononuclear Cell Nephropathy Renal Tubule, Pigmentation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 92

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 2 | 3 | 8 | 3 | 3 | 3 | 4 | 3 | 2 |   |
|                                | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 8 | 1 | 3 | 3 | 3 | 3 | 9 | 7 | 6 | 9 | 6 | 1 | 1 | 2 | 1 | 6 |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>3000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|                                | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |   |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| Urinary Bladder                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

females  
(cont...)

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
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 A .. Autolysis precludes evaluation  
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 1-4 .. Lesion qualified as:  
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 2) Mild 4) Marked  
 Page 93



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6               | 0 |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6               | 5 |
|                                | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1               | 9 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| ANIMAL ID                      | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               | 0 |
| <b>3000 PPM</b>                | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2               | 3 |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9               | 0 |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9               | 0 |
|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |

|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|-----------|------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hepatocyte, Hypertrophy               | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 | <b>10</b> | <b>1.3</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatocyte, Vacuolization Cytoplasmic |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 | <b>4</b>  | <b>3.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Kupffer Cell, Pigmentation            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 | <b>2</b>  | <b>2.5</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                             |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Accessory Spleen                      |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | X         | X          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Fat, Necrosis                         |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 | <b>5</b>  | <b>3.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreas                              |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | +         | +          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy                               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 1 |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Cyst                                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | X | X         |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Acinus, Cytoplasmic Alteration        |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Acinus, Hyperplasia, Focal            |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 2 | 1         | 2          | 1 | 1 | 1 |   | 1 |   | 1 |   | 1 | 3 |   | 1 |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>17</b> | <b>1.5</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>10</b> |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>1</b>  | <b>3.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>1</b>  | <b>2.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | +         | +          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>50</b> |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach                  |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | +         | +          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Edema                                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ulcer                                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Epithelium, Hyperplasia               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 3 |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>2</b>  | <b>4.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>2</b>  | <b>3.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>2</b>  | <b>3.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                    |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | + | +         | +          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Edema                                 |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Erosion                               |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |           |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>1</b>  | <b>2.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | <b>1</b>  | <b>1.0</b> |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**CARDIOVASCULAR SYSTEM**

|       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +         |
|       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>50</b> |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7                              | 7         | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |          |
| 3                              | 3         | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5 |          |
| 2                              | 2         | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |          |
| <hr/>                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| <b>3000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|                                | 2         | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |          |
|                                | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |          |
|                                | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |          |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Thyroid Gland                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| C-cell, Hyperplasia          |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   | 2 |    | 5 1.4 |
| Follicle, Cyst               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |    | 2     |
| Follicular Cell, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |    | 2 2.0 |

**GENERAL BODY SYSTEM**  
 NONE

**GENITAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Clitoral Gland        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |    | 2     |
| Hyperplasia           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2 2.0 |
| Hyperplasia, Focal    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 5 2.0 |
| Inflammation, Chronic | 3 |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 2.8 |
| Ovary                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Cyst                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |    | 5     |
| Uterus                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |
| Decidual Reaction     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 3.0 |
| Hyperplasia, Cystic   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 9 2.1 |
| Vagina                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4     |

**HEMATOPOIETIC SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                 |  |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |                 |  |
|                                | 7           | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0 |                 |  |
|                                | 3           | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5               |  |
|                                | 2           | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |                 |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |  |
| <b>3000 PPM</b>                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |  |
|                                | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3               |  |
|                                | 7           | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |  |
|                                | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | <b>* TOTALS</b> |  |

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--|
| Mammary Gland<br>Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |  |
|                              | 4 | 2 | 2 | 2 | 2 | 4 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 4 | 1 | 3 |   | 46 2.4 |  |
| Skin                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49     |  |

**MUSCULOSKELETAL SYSTEM**

|                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |       |  |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|--|
| Bone<br>Osteopetrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50    |  |
|                       |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0 |  |

**NERVOUS SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |  |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|--|
| Brain<br>Compression | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |  |
|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   | 2  | 8 3.3 |  |
| Peripheral Nerve     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2     |  |
| Spinal Cord          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2     |  |

**RESPIRATORY SYSTEM**

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |       |  |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|--|
| Lung<br>Edema<br>Foreign Body | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |       |  |
|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 2.0 |  |
|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1     |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 99  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0             | * TOTALS      |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|---------------|
|  | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 6 | 6             |               |
|  | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6 | 5 |   |               |               |
|  | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9 |   |               |               |
| <b>FISCHER 344 RATS FEMALE</b>   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |               |               |
| <b>3000 PPM</b>  | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |               |               |
| ANIMAL ID  | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |               |               |
|  | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |               |               |
|  | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |               |               |
| Infiltration Cellular, Histiocyte<br>Inflammation, Chronic<br>Metaplasia, Osseous<br>Alveolar Epithelium, Hyperplasia<br>Serosa, Hyperplasia | 1 | 2 | 1 | 1 | 1 | 1 |   |   |   |   | 1 | 1 | 1 | 1 | 2 |   | 1 | 1 | 1 |   |   | 1 | 1 | 1 |   | <b>34 1.1</b> |               |
|  | 1 |   | 1 | 1 |   |   |   |   |   |   | 1 | 1 | 1 | 1 |   |   | 1 | 1 | 1 | 1 |   |   |   |   |   | <b>21 1.0</b> |               |
|  | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   | <b>2 1.0</b>  |               |
|  |   | 1 |   |   | 1 | 3 |   |   |   |   |   | 1 |   |   |   |   | 1 |   |   |   |   |   |   |   |   | <b>7 1.6</b>  |               |
|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | <b>1 2.0</b>  |               |
| Nose   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |               |
| Foreign Body   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>3</b>      |               |
| Trachea  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b>     |               |
| <b>SPECIAL SENSES SYSTEM</b>   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |               |
| Eye  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +             | <b>50</b>     |
| Cataract   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>2 2.5</b>  |
| Retina, Degeneration   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>2 3.0</b>  |
| Harderian Gland  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +             | <b>50</b>     |
| <b>URINARY SYSTEM</b>  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               |               |
| Kidney   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +             | <b>50</b>     |
| Infarct  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 1.0</b>  |
| Infiltration Cellular, Mononuclear Cell  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 2.0</b>  |
| Nephropathy  | 1 | 1 | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>24 1.1</b> |
| Renal Tubule, Pigmentation   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |               | <b>1 3.0</b>  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |   |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 0               |   |
|                                | 3 | 3 | 3 | 3 | 3 | 3 | 8 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 6               | 5 |
|                                | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 7 | 7 | 2 | 2 | 2 | 2 | 9 | 5 | 1 | 1 | 1 | 1 | 3 | 6 | 6 | 6 | 1 | 9               |   |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |   |
| <b>3000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |   |
| ANIMAL ID                      | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3               |   |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |   |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0               |   |
|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>* TOTALS</b> |   |
| Urinary Bladder                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b>       |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
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 I .. Insufficient tissue  
 M .. Missing tissue  
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 2) Mild 4) Marked  
 Page 101

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females (cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
|             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
| 7           | 5         | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 0                 |
| 3           | 6         | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 0                 |
| 2           | 9         | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 0                 |

  

| FISCHER 344 RATS FEMALE<br>9000 PPM | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females (cont...) |
|-------------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
|                                     | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                   |
| 3                                   | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                 |
| 0                                   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2                 |
| 1                                   | 2         | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2                 |

**ALIMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | A | + | + | + | + | + |
| Liver                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |
| Basophilic Focus                  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Clear Cell Focus                  | X |   | X |   |   |   | X |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X |   | X |
| Cyst                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Eosinophilic Focus                |   | X |   | X |   | X | X |   |   |   | X | X |   |   | X | X |   |   | X | X |   | X | X |   | X |
| Hemorrhage                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hepatodiaphragmatic Nodule        |   | X |   |   |   | X | X |   | X |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   | X |
| Infiltration Cellular, Mixed Cell |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mixed Cell Focus                  | X |   | X |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   | X | X |   |
| Bile Duct, Hyperplasia            |   |   |   |   | 1 |   | 1 |   |   |   |   |   | 1 | 1 | 2 |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
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TDMS No. 99007 - 05  
 Test Type: CHRONIC  
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 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
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 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 5         | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 |                      |
| 3                              | 6         | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 |                      |
| 2                              | 9         | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |                      |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>9000 PPM</b>                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Centrilobular, Necrosis               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |
| Hepatocyte, Degeneration              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |
| Hepatocyte, Hypertrophy               | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 1 | 2 | 1 | 1 |   |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Oral Mucosa                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Pancreas                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   |   |   |
| Atrophy                               |   |   | 1 | 2 | 2 |   |   | 2 |   |   | 1 | 1 |   |   | 1 | 2 |   |   | 1 | 2 |   |   | 1 |   |   |   |   |   |   |   |
| Cyst                                  | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |
| Acinus, Hyperplasia, Focal            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X |   |   | X |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Salivary Glands                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   |   |   |
| Atrophy                               |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Forestomach                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   |   |   |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Stomach, Glandular                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |   |   |   |   |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tooth                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 Page 103  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked





TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
|                                | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| <b>9000 PPM</b>                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
|                                | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
|                                | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

females (cont...)

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pars Distalis, Cyst               | X |   | X | X |   | X | X | X |   |   |   |   | X | X | X |   |   | X | X | X | X | X |   |   |   |
| Pars Distalis, Hyperplasia, Focal | 2 |   | 1 | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   | 2 |   |   |   |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia               |   |   |   |   |   | 2 |   |   |   |   |   |   | 1 |   |   | 1 |   |   |   |   |   |   |   |   | 1 |
| Follicle, Cyst                    |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

**GENERAL BODY SYSTEM**  
 NONE

**GENITAL SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland                           | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |
| Hyperplasia, Focal                       |   |   |   |   | 3 |   |   |   | 3 |   |   |   | 2 |   | 3 |   |   |   |   |   |   |   |   |   |   |
| Inflammation, Chronic                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Ovary                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst                                     |   |   | X | X |   |   |   |   |   | X |   |   |   |   | X |   |   |   |   | X |   |   |   |   |   |
| Corpus Luteum, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Uterus                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Cystic                      | 1 | 3 |   |   |   |   |   |   |   |   |   | 3 | 3 |   |   |   |   |   |   |   |   |   | 2 |   |   |
| Inflammation, Suppurative                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Myometrium, Hypertrophy                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vagina                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked







TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|   | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |   |
|   | 3 | 6 | 3 | 3 | 3 | 6 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|   | 2 | 9 | 2 | 2 | 2 | 6 | 1 | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 3 | 2 | 6 | 6 | 6 | 6 | 6 | 6 |   |
| <b>FISCHER 344 RATS FEMALE</b>              | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| <b>9000 PPM</b>                             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| ANIMAL ID                                   | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |   |
|   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |   |
| Inflammation, Suppurative Nephropathy       | 1 | 1 | 1 | 1 | 1 |   | 1 |   | 1 |   |   | 1 |   | 1 | 1 | 3 |   |   | 1 |   | 1 | 1 | 1 | 1 |   |   |
| Renal Tubule, Accumulation, Hyaline Droplet |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Renal Tubule, Pigmentation                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |
| Transitional Epithelium, Hyperplasia        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |
| Urinary Bladder                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |

females (cont...)

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked















TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | * TOTALS |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
|                                | 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 4 5 7 7 7 7 7 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                | 3 3 3 3 3 3 3 3 3 3 3 3 6 3 3 3 3 7 6 3 3 3 3 3 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                | 2 2 2 2 2 6 6 6 6 6 2 2 3 2 2 2 2 4 5 2 2 2 2 2 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| <b>FISCHER 344 RATS FEMALE</b> | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| <b>9000 PPM</b>                | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
| ANIMAL ID                      | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |
|                                | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |          |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |     |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Hemorrhage                        | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2   | 2.0 |
| Infiltration Cellular, Histiocyte |   | 1 |   | 1 | 1 |   | 1 |   | 2 | 1 | 1 | 1 |   | 1 |   | 4 | 1 | 1 | 1 | 1 | 1 |   |   |    | 37  | 1.1 |
| Inflammation, Chronic             |   | 1 | 1 |   | 1 | 1 |   |   |   |   |   |   |   |   | 1 | 4 |   | 1 | 1 |   | 1 | 1 | 1 | 19 | 1.2 |     |
| Metaplasia, Osseous               |   |   |   | 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  | 1.0 |     |
| Alveolar Epithelium, Hyperplasia  |   |   |   | 1 |   |   |   |   | 3 |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   | 5  | 1.6 |     |
| Serosa, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 2.0 |     |
| Nose                              |   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |     |
| Foreign Body                      |   |   |   | X |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   | 2  |     |     |
| Inflammation, Chronic             |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   | 1  | 1.0 |     |
| Trachea                           |   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |     |

**SPECIAL SENSES SYSTEM**

|                      |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |     |
|----------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Eye                  |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Cataract             |  |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 2.0 |
| Retina, Degeneration |  |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  | 3.0 |
| Harderian Gland      |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |     |
| Zymbal's Gland       |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |     |

**URINARY SYSTEM**

|        |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |  |
|--------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|
| Kidney |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |  |
| Cyst   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                                 | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|   | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
| 7   | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 0        |
| 3   | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 3 | 3 | 3 | 0        |
| 2   | 2         | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 4 | 5 | 2 | 2 | 2 | 2 | 2 | 0        |
| <b>FISCHER 344 RATS FEMALE</b>              | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
| <b>9000 PPM</b>                             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|   | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        |
|   | 2         | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |
|   | 6         | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |
| Inflammation, Suppurative                   |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 | 1 2.0    |
| Nephropathy                                 | 1         | 1 |   |   | 1 | 1 | 2 | 1 |   | 1 | 2 |   |   | 1 | 2 | 1 | 1 |   | 1 | 1 | 1 | 1 | 1 | 3 | 33 1.2   |
| Renal Tubule, Accumulation, Hyaline Droplet |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 2.0    |
| Renal Tubule, Pigmentation                  |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0    |
| Transitional Epithelium, Hyperplasia        |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   | 2 2.0    |
| Urinary Bladder                             | +         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 117



TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |                      |
| 2                              | 2         | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |                      |
| 9                              | 9         | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |                      |
| .....                          |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>25000 PPM</b>               | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |   |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Necrosis, Focal                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |  |
| Bile Duct, Hyperplasia                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Hepatocyte, Degeneration              | 1 | 2 | 1 |   |   |   | 1 | 2 |   |   |   |   | 1 | 1 |   |   | 1 | 1 |   |   | 2 | 2 |   |   | 1 |   |  |
| Hepatocyte, Hypertrophy               | 2 | 2 | 1 | 1 |   |   |   | 2 | 3 |   |   | 2 | 2 | 2 | 2 |   |   | 2 | 1 | 2 | 2 | 3 | 1 | 3 | 2 | 2 |  |
| Hepatocyte, Vacuolization Cytoplasmic |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4 |  |
| Kupffer Cell, Pigmentation            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Mesentery                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Accessory Spleen                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Fat, Necrosis                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Pancreas                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Atrophy                               | 3 |   |   | 1 |   |   |   |   |   |   |   |   |   | 1 |   |   | 3 | 2 |   |   | 1 |   |   | + |   |   |  |
| Cyst                                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Acinus, Cytoplasmic Alteration        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Salivary Glands                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Atrophy                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Stomach, Forestomach                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Edema                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |  |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |  |
| Epithelium, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |  |
|                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Stomach, Glandular                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Erosion                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |  |
| Ulcer                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |  |
| .....                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Tongue                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                          | 0   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|                                      | 7 7 7 7 1 6 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FISCHER 344 RATS FEMALE<br>25000 PPM | 2 2 2 2 2 8 3 3 7 3 2 2 2 2 2 3 0 3 3 3 3 3 1 4 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 9 9 9 9 2 4 3 3 5 3 9 9 9 6 9 2 1 2 2 2 2 2 6 1 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                            | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 0 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 25000 PPM                            | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ANIMAL ID                            | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|                                      | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

females (cont...)

Inflammation, Granulomatous

**CARDIOVASCULAR SYSTEM**

|                |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Heart          | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cardiomyopathy | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ENDOCRINE SYSTEM**

|                                   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex                    | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accessory Adrenal Cortical Nodule | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Angiectasis                       |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Degeneration, Fatty               | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia, Focal                | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hypertrophy, Focal                | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Necrosis                          | 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adrenal Medulla                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hyperplasia                       | 1     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Islets, Pancreatic                | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Parathyroid Gland                 | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pituitary Gland                   | + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Angiectasis        | 4 3     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pars Distalis, Cyst               | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked







TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID        |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  | females<br>(cont...) |  |
|--------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----------------------|--|
|                                | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>1<br>2<br>3 | 0<br>6<br>8<br>4 | 0<br>7<br>3<br>3 | 0<br>7<br>3<br>3 | 0<br>5<br>7<br>5 | 0<br>7<br>3<br>3 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>6 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>2 | 0<br>7<br>3<br>0 | 0<br>7<br>3<br>3 | 0<br>7<br>3<br>3 | 0<br>7<br>3<br>3 | 0<br>7<br>3<br>3 | 0<br>7<br>3<br>1 | 0<br>7<br>6<br>4 | 0<br>5<br>6<br>8 |                      |  |
| <b>FISCHER 344 RATS FEMALE</b> | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                    |  |
| <b>25000 PPM</b>               | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                | 0                    |  |
|                                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                | 3                    |  |
|                                | 5                | 5                | 5                | 5                | 5                | 5                | 5                | 5                | 5                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 6                | 7                | 7                | 7                | 7                | 7                    |  |
|                                | 1                | 2                | 3                | 4                | 5                | 6                | 7                | 8                | 9                | 0                | 1                | 2                | 3                | 4                | 5                | 6                | 7                | 8                | 9                | 0                | 1                | 2                | 3                | 4                | 5                |                      |  |

Thymus Atrophy +  
 3

**INTEGUMENTARY SYSTEM**

Mammary Gland Hyperplasia +  
 3 3 2 3 3 3 4 1 4 1 1 2 3 2 4 1 4 +

Skin Edema Hyperkeratosis +  
 4

**MUSCULOSKELETAL SYSTEM**

Bone +

Skeletal Muscle Hemorrhage Inflammation, Suppurative +  
 4

**NERVOUS SYSTEM**

Brain Compression Hemorrhage Necrosis +  
 3 3 1  
 4  
 4

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 123

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|--------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                                | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| 7                              | 7         | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 5 |                      |
| 2                              | 2         | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6 |                      |
| 9                              | 9         | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8 |                      |
| <b>FISCHER 344 RATS FEMALE</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
| <b>25000 PPM</b>               | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                                | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |                      |
|                                | 5         | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |                      |
|                                | 1         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |                      |

Peripheral Nerve

+ +

Spinal Cord

+ +

**RESPIRATORY SYSTEM**

|                                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage                          | 3 | 3 | 2 | 4 |   |   |   |   |   |   | 3 |   |   | 2 | 2 |   | 3 |   |   |   |   |   |   |   |
| Infiltration Cellular, Histiocyte   |   | 1 | 1 | 1 |   | 1 | 1 | 1 |   | 1 | 1 | 1 |   | 1 | 1 | 1 | 1 | 2 | 1 |   |   | 2 | 2 | 1 |
| Inflammation, Chronic               |   |   | 2 |   |   |   |   | 2 |   |   |   |   |   | 1 | 1 |   |   | 1 | 2 |   |   |   |   |   |
| Metaplasia, Osseous                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Alveolar Epithelium, Hyperplasia    |   |   |   |   |   | 1 |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Serosa, Hyperplasia                 |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nose                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Foreign Body                        | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |
| Inflammation, Chronic               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Respiratory Epithelium, Hyperplasia |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Trachea                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**SPECIAL SENSES SYSTEM**

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cataract             |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   | 4 |   |   |
| Retina, Degeneration |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   |   |   | 4 |   |   |

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TDMS No. 99007 - 05  
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**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

|                                | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                  |                |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------|----------------|
|                                | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                  |                |
|                                | 7           | 7 | 7 | 7 | 1 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                  |                |
|                                | 2           | 2 | 2 | 2 | 2 | 8 | 3 | 3 | 7 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 4 | 6                |                |
|                                | 9           | 9 | 9 | 9 | 2 | 4 | 3 | 3 | 5 | 3 | 9 | 9 | 9 | 6 | 9 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 8                |                |
| <b>FISCHER 344 RATS FEMALE</b> | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                |                |
| ANIMAL ID                      | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                |                |
| <b>25000 PPM</b>               | 3           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                |                |
|                                | 5           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7                | <b>females</b> |
|                                | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | <b>(cont...)</b> |                |

Harderian Gland  
 Inflammation, Chronic

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |

**URINARY SYSTEM**

Kidney  
 Glomerulosclerosis  
 Nephropathy  
 Renal Tubule, Accumulation, Hyaline Droplet  
 Renal Tubule, Necrosis  
 Renal Tubule, Pigmentation

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |
| 2 | 2 |   | 2 |   | 1 | 1 |   | 1 | 2 | 1 | 1 | 1 |   | 2 | 1 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 2 | 1 |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |

Urinary Bladder

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked









TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
|                                | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7               |
|                                | 3 | 3 | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3               |
|                                | 2 | 2 | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 2 | 2               |
| <b>FISCHER 344 RATS FEMALE</b> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| <b>25000 PPM</b>               | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0               |
| ANIMAL ID                      | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4               |
|                                | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0               |
|                                | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | <b>* TOTALS</b> |

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |            |            |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|------------|
| Pars Distalis, Hyperplasia, Focal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>9</b>  | <b>1.8</b> |            |
| Pars Intermedia, Angiectasis      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2</b>   | <b>2.5</b> |
| Pars Intermedia, Cyst             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>2</b>  |            |            |
| Thyroid Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |            |            |
| C-cell, Hyperplasia               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>5</b>  | <b>1.2</b> |            |
| Follicle, Cyst                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>1</b>  |            |            |

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           |           |            |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-----------|------------|
| Clitoral Gland         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |           |            |
| Cyst                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>  |            |
| Inflammation, Chronic  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>2</b>  | <b>3.0</b> |
| Ovary                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>49</b> |           |            |
| Cyst                   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | <b>8</b>  |           |            |
| Uterus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | <b>50</b> |           |            |
| Cyst                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>  |            |
| Hyperplasia, Cystic    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>13</b> | <b>2.0</b> |
| Cervix, Cyst, Squamous |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>  | <b>3.0</b> |
| Vagina                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |           | <b>1</b>  |            |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

TDMS No. 99007 - 05  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: RATS/F 344

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008  
 Time Report Requested: 08:34:31  
 First Dose M/F: 04/21/03 / 04/21/03  
 Lab: SRI

| DAY ON TEST  | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          | 0 |
| 7  | 7         | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 0        |   |
| 3  | 3         | 1 | 3 | 1 | 3 | 3 | 3 | 7 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 0        |   |
| 2  | 2         | 6 | 2 | 8 | 6 | 6 | 6 | 8 | 6 | 2 | 3 | 2 | 2 | 2 | 3 | 3 | 6 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 0        |   |
| .....  |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |
| <b>FISCHER 344 RATS FEMALE</b><br><b>25000 PPM</b> | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|  | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|  | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0        |   |
|  | 7         | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0        |   |
| 6  | 7         | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |          |   |

**HEMATOPOIETIC SYSTEM**

|                                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--|
| Bone Marrow                        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |  |
| Hyperplasia                        |   |   | 3 | 3 |   |   |   |   |   |   | 2 |   |   |   |   |   |   | 3 |   |   |   |   |   |   | 6 2.5  |  |
| Infiltration Cellular, Histiocyte  |   |   |   | 1 |   |   |   |   |   |   |   | 2 |   |   |   |   |   |   |   |   |   |   |   |   | 3 2.0  |  |
| Myelofibrosis                      |   |   |   |   |   |   |   | 4 |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   | 5 3.2  |  |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Lymph Node                         |   | + |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | 8      |  |
| Mediastinal, Hemorrhage            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |  |
| Mediastinal, Hyperplasia, Lymphoid |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 2.5  |  |
| Mediastinal, Pigmentation          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |  |
| Pancreatic, Hemorrhage             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2 |   |   |   | 1 2.0  |  |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Lymph Node, Mandibular             | M | M | M | M | M | + | + | + | M | + | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 5      |  |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Lymph Node, Mesenteric             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49     |  |
| Ectasia                            |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |  |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |   |   |   |   | 3 1.7  |  |
| Hyperplasia, Lymphoid              |   |   | 2 |   |   |   |   |   |   | 2 |   |   |   | 2 |   | 2 |   | 2 |   |   |   | 2 |   |   | 9 2.0  |  |
| .....                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Spleen                             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50     |  |
| Fibrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3 |   |   |   |   |   |   |   |   |   | 2 2.5  |  |
| Hematopoietic Cell Proliferation   | 2 | 3 | 3 | 3 | 2 | 2 | 2 |   |   |   | 3 | 3 | 2 | 2 |   | 1 | 1 | 2 | 1 | 2 |   |   | 2 | 3 | 35 2.0 |  |
| Hemorrhage                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |  |
| Infiltration Cellular, Mixed Cell  |   |   |   |   |   |   |   |   |   |   |   |   | 4 |   |   |   |   |   |   |   | 4 |   |   |   | 3 4.0  |  |
| Necrosis                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 4.0  |  |
| Lymphoid Follicle, Atrophy         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 3.0  |  |

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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